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Regulatory Impact Assessment of Proposed Effluent Guidelines for the Pharmaceutical Manufacturing Industry

Final Report

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EXECUTIVE SUMMARY

INTRODUCTION

This report has been prepared to comply with Executive Order 12866, which requires federal agencies to assess the costs and benefits of each significant rule they propose or promulgate. The regulations for the pharmaceutical industry, which are proposed by the U.S. Environmental Protection Agency (EPA, or the Agency), meet the Order's definition of a significant rule. The Agency has assessed both costs and benefits of the proposed rule, as presented in this Regulatory Impact Assessment (RIA).

BACKGROUND

Overview of the Pharmaceutical 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). 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. EPA estimates that approximately 364 of the 1,343 pharmaceutical facilities are either direct or indirect effluent dischargers and would be affected by the revised effluent regulations. The Section 308 Survey obtained data from 244 of these establishments.

According to the U.S. Department of Commerce and other sources, the pharmaceutical industry is considered a growth industry with above average profits, which has consistently maintained a positive trade balance. The industry has a high concentration ratio and tends to be vertically integrated. High R&D costs, FDA regulations, and other factors serve as barriers to entry into the industry, although exit and entry rates into the industry are quite high.

Demand conditions vary significantly from a low level of price sensitivity for prescription drugs to a more standard model of consumer demand for OTC drugs. The degree of substitutability among pharmaceuticals ranges from reduced substitutability for many patented drugs to substantial substitutability for OTC drugs. These factors seem to lead to price inelasticity for pharmaceuticals as a whole, although demand for specific drug products might be relatively elastic. Many specific companies do appear to have sufficient market power to pass through regulatory costs, however, this RIA uses the conservative assumption that manufacturers cannot pass through compliance costs.

Regulatory History

The Clean Water Act (CWA), 33 U.S.C. 1251 et seq., 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 EPA is required to issue effluent limitations guidelines, pretreatment standards, and new source performance standards for "categories and classes of point sources" [Section 301(b)(2)(A)]. The Pharmaceutical Manufacturing Category is one such category. A study of dischargers of hazardous waste indicated that the pharmaceutical industry is indeed a major discharger of hazardous pollutants. Hence, a schedule was established for the promulgation of effluent limitations guidelines and standards for the pharmaceutical manufacturing industry.

Sources of Data

Prior to the data gathering for this regulation, EPA's last detailed information gathering effort involving the pharmaceutical industry occurred in 1978. Thus EPA conducted a new survey for this regulation, 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 would potentially be affected by EPA's proposed effluent guidelines.

Another major data source used to supplement the survey data in the RIA 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.

NEED FOR REGULATION

Executive Order 12866 requires that the Agency identify the need for the regulation being proposed. The discharge of pollutants into effluent and hence into surface water and the emission of air pollutants pose a threat to human health and the environment. Risks from these emissions and discharges include increases in cancer risk, other adverse noncancer health effects on humans, and degradation of the environment.

The need for effluent guidelines for this source category arises from the failure of the marketplace to provide the optimal level of pollution control desired by society. Correction of such a market failure might require federal regulation. The Office of Management and Budget defines market failures as the presence of externalities, natural monopolies, and inadequate information. Environmental pollution is a classic example of the presence of externalities.

Furthermore, legal requirements also prevail. The regulations are proposed under the authorities of Sections 301, 304, 306, 307, and 501 of the Clean Water Act (the Federal Water Pollution Control Act Amendment of 1972, 33 U.S.C. 1251 et seq., as amended by the Clean Water Act of 1987, Pub. L. 100-4, also referred to as the CWA or the Act) and under the authority of Section 112 of the Clean Air Act Amendments of 1990.

TECHNOLOGY OPTIONS AND REGULATORY ALTERNATIVES

A number of alternatives are available to pharmaceutical facilities that would allow them to meet more stringent effluent limits. Key alternatives are advanced biological treatment and distillation. Advanced biological treatment is used in the pharmaceutical manufacturing industry to treat biochemical oxygen demand (BOD_5), chemical oxygen demand (COD), and total suspended solids (TSS) as well as to degrade various organic constituents and reduce ammonia. They can be aerobic or, more rarely, anaerobic processes. The four most common aerobic treatment technologies in the industry are activated sludge, aerated lagoon, trickling filter, and rotating biological contactor (RBC). Distillation is used to remove gases and/or organic chemicals from wastewater streams by injecting steam into a tray or packed distillation column. Distillation is an effective treatment for a wide range of aqueous streams containing organics and ammonia. Other approaches include multimedia filtration, polishing ponds, cyanide destruction, granular activated carbon adsorption, pH adjustment/neutralization, and equalization.

Based on these technologies currently used in the pharmaceutical industry, EPA has developed a set of regulatory options, which 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 or natural extractive processes or that are formulators of pharmaceutical products). For direct dischargers, the technologies are then further broken down into BPT, BCT, BAT, and NSPS options; for indirect dischargers, PSES and PSNS technology options are examined.

Table ES-1 presents the 37 regulatory options considered by EPA and defines the technologies associated with each option. 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.

TABLE ES-1

REGULATORY OPTIONS CONSIDERED IN THE REGULATORY 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 ES-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, 1995a), 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.

- 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).

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

ECONOMIC IMPACTS AND SOCIAL COSTS

This section presents an overview of the EIA methodology and describes the principle models used: the cost annualization model, the facility-level model and the firm-level model.

The cost annualization model estimates the annual compliance cost to the facility of new pollution control equipment and operations by allocating the capital investment over the lifetime of the equipment, incorporating 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, and including annual operating and maintenance (O&M) costs.

The annualized costs for the selected regulatory options are given in Table ES-2. 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 $).

TABLE ES-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.

Facility-Level Analysis

The facility-level analysis identifies facilities that are likely to close as a result of incremental compliance cost. In the facility-level analysis, the 65 facilities (representing a total of 72 facilities) that certified in the Section 308 Pharmaceutical Survey that the regulation would not affect them are automatically placed in the "no closure" category of the model. Additionally, 76 firm/facilities also are placed in the "no closure" category. These are firms that indicated in the Section 308 survey that they and their facility were the same entity (i.e., the firm owns only one facility). Impacts on firm/facilities are evaluated in the firm-level analysis. The facility closure model thus evaluates the remaining 134 of the 282 facilities in the survey universe.

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) assets and fixed (i.e., long-term) assets. Data for the facility-level analysis is either taken directly from the 308 Pharmaceutical Survey or estimated based on data that was provided by other facilities. Only those facilities estimated to remain open without any incremental regulatory costs (i.e., remain open in the baseline analysis) are considered in the analysis to identify postregulatory impacts.

Based on the methodology outlined above, it is estimated that none of the selected regulatory options is expected to result in any facility closures.

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)[1] and the interest coverage ratio (ICR)[2]. 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 any regulatory costs are considered) is evaluated after the projected baseline facility closures are accounted for. In the postcompliance analysis, those firms determined to be viable in the baseline analysis are investigated to determine the firms' financial condition following compliance with each option individually as well as the selected options in combination. Data from the Section 308 survey and engineering cost estimates are used to calculate baseline and postcompliance ROAs and ICRs. Postcompliance ROAs and ICRs are adjusted to reflect annual compliance costs estimated at the facility level as well as losses in income and liquidation of assets necessitated by facility closures, if any.

To evaluate the baseline and postcompliance 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 are judged to be vulnerable to financial failure.

The standard postcompliance analysis, referred to as Postcompliance Analysis 1, evaluates impacts on firms that are not found to be vulnerable in the baseline analysis[3]. For these healthier companies, if either of the postcompliance ROA and ICR values fall below the 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

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[1]Net income divided by total assets.

[2]Earnings before interest and taxes divided by interest payments.

[3]Sensitivity analyses were run to determine the potential for impacts on firms estimated likely to fail in the baseline. These analyses determined the magnitude of change in ROA, ICR, or net income, should the firm not fail as predicted. Most such firms showed no substantial change in these variables.

result of the regulation. Table ES-3, which presents the results of Postcompliance Analysis 1 under the selected regulatory options, shows that only two firms with A/C indirect discharging facilities and one firm with B/D indirect discharging facilities are expected to experience significant impacts as a result of compliance costs. Overall, these indirect discharging firms represent 2.3 percent of all affected pharmaceutical firms that are not estimated to fail in the baseline analysis.

Finally, a profitability analysis was undertaken to determine impacts on profitability among firms analyzed in Postcompliance Analysis 1 using percentage change in ROA under the selected regulatory options to assess impacts on profitability (a change of more than 5 percent is considered a major impact). Fifteen firms are estimated to experience major impacts, although only one firm will have impacts of greater than 50 percent. Including the firms that certified they would experience no impacts from the effluent guideline, only 11 percent of firms in the postcompliance analysis are expected to experience major impacts short of firm failure. Note that these impacts would be much less if it was assumed that firms could pass through some of their compliance costs in the form of price increases. Additionally these 15 firms have a very high baseline median ROA, so many would continue to have adequate to good returns.

Employment and Community-Level Analysis

The employment and community-level analysis investigates employment losses, community-level impacts from these losses, and employment gains resulting from compliance with the effluent guidelines (Baseline employment losses are determined and subtracted from current employment before incremental employment losses are calculated). 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 and firm failures estimated in the facility-level and firm-level analyses. 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

TABLE ES-3

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#2A 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#1A, and B/D Indirect facilities under option PSES-B/D#1A.
** 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.

measures the extent of impacts in other industries as a function of impacts in the primary industry. Employment gains are calculated for three areas: manufacture of the compliance equipment, installation of the equipment, and operation and maintenance of the equipment.

The baseline impacts from the analysis on primary employment before any compliance costs are incurred total 14,381 jobs estimated to be lost, out of a total employment of 147,804 workers[4] (9.7 percent of total employment). 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.

No employment losses were projected to occur as a result of regulatory options for direct dischargers. For indirect dischargers, however, total projected primary employment losses resulting from the selected regulatory options were 78 full-time equivalent (FTE) positions among A/C indirects and 13 FTEs among B/D indirects, for a total of 91 FTEs or 0.07 percent of total employment for the affected portion of the industry. Secondary losses were predicted to be 541 FTEs.

None of these losses is expected to result in a change of employment rates of more than 1 percent in the affected communities.

The sum of primary and secondary employment gains is calculated to range from 218 FTEs to 2,890 FTEs. Net gains and losses thus range from a loss of 323 FTEs to a gain of 2,349 FTEs.

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

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

guidelines can therefore affect the balance of trade. To estimate impacts on trade, the value of 1990 pharmaceutical exports is estimated for facilities expected to close under the selected regulatory options. 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 under the selected regulatory options. The one firm/facility that is predicted to close as a result of the effluent guidelines has pharmaceutical exports totaling $0.08 million ($0.09 million 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.

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.

Small firms make up 76 percent of the 190 firms in the survey universe. The largest percentage of firms are in the 100-499 employees size group (37 percent of all firms in the survey universe).

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. Monitoring costs total $9.0 million ($10.3 million 1994 $) annually, and are 15 percent of the total annual compliance cost for the selected options. Large firms incur the largest proportion of monitoring costs (61 percent of total monitoring costs).

No significant alternatives to the proposed rule will substantially reduce impacts on small entities, thus the Agency believes the stated objectives of the Clean Water Act are met with this proposed rule and the impacts to small firms have been considered, where possible.

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, although only 2 percent of small firms are affected in this manner. In addition, 14 of 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 size category, the total present value of compliance costs as a percentage of the present value of net income is smaller among small firms than among large firms. Over all firms, the present value of compliance costs is less than 1 percent of the present value of net income.

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 smaller, on average, among small firms than among large firms; thus, impacts to small firms are not expected to be disproportionate to those for large firms.

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.

For all the selected regulatory options, the ratio of compliance costs to total pharmaceutical costs averaged 1.6 percent. Most facilities would incur compliance costs less than 1 percent of total pharmaceutical costs. Only three facilities (1 percent of all facilities) would incur compliance costs greater than 10 percent of total pharmaceutical costs.

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. It was further determined that individuals 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. These groups include Hispanics, young adults, African Americans, young children, and the elderly. Thus, 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), impacts on mass consumers of drugs such as HMOs, governments, and, indirectly, third-party insurers should be minimal.

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 ($674 thousand 1994 $) difference (for A/C direct dischargers), depending on the type of facility. The maximum $590 thousand 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.

Social Costs of Regulation

A major component of social cost (beyond the cost to industry of compliance) is the cost to government of providing these tax savings to industry. In addition, there are other monetary and nonmonetary outlays made by government. Government administrative costs and costs of reallocating displaced workers are two additional monetary costs. Nonmonetary costs include losses in consumers' or producers' surpluses in product markets, discomfort or inconvenience, loss of time, and slowing the rate of innovation. The social costs estimated here, which include compliance costs to industry and the costs of government tax subsidies), therefore, are a very

large portion of, but not the true total social cost of the proposed regulation. The costs reported here are thus only a close estimate of this true cost.

To model the social costs, the entire annual *pre-tax* cost of the proposed effluent guideline is estimated, using the same time period (16 years) and the discount rate advocated by OMB as appropriate for annualizing social costs of 7 percent (rather than the higher, average discount rate of 11.4 percent reported by Section 308 respondents).

The estimate of total annual social costs for all selected options is shown in Table ES-4. Total social costs resulting from the proposed effluent guideline are estimated to be $108.4 million ($123.9 million 1994 $) per year.

POLLUTION REDUCTION

EPA has established final raw, current, and proposed loadings for nonconventional constituents that currently are candidates for regulation in the pharmaceutical industry. EPA calculated these final loadings using data from the Section 308 Survey database and Radian's WATER.DBF, STEAM.DBF, and AIR.DBF treatability databases.

Because the Agency believes, however, that more air emissions are occurring from these facilities than were reported, EPA developed an independent estimate of these loadings using the EPA's Office of Air Quality Planning and Standards (OAQPS) WATER7 model. The WATER7 model evaluates several pollutant pathways including volatilization, biodegradation, and adsorption onto solids for individual waste constituents from a model wastewater treatment train.

Table ES-5 presents estimates of water and air pollutant loadings and reductions for the selected regulatory scenario.

TABLE ES-4

COMPLIANCE COSTS FOR SELECTED REGULATORY OPTIONS (1990 $)

Option Number	Total Capital Costs	Total O&M Costs	Total Pretax Annualized Costs	Average Annual Cost per Facility*
BAT-A/C#2	$56,392,127	$35,689,088	$41,658,626	$1,735,776
BAT-B/D#1	$644,446	$1,104,801	$1,173,021	$83,787
PSES-A/C#1	$70,795,915	$46,441,499	$53,935,789	$612,907
PSES-B/D#1	$25,160,649	$8,956,179	$11,619,626	$75,945
Total**	$152,993,137	$92,191,568	$108,387,062	$388,484

* Total Pretax 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. estimates of capital and operating costs for pollution control equipment.

TABLE ES-5

ESTIMATED POLLUTANT LOADINGS BY TYPE OF FACILITY

Regulatory Option	Raw Load (lb)	Current Load (lb)	Total Load Reduction (lb)
A/C Direct Dischargers			
BAT-A/C#1	77,906,785	5,133,649	4,894,776
BAT-A/C#2			18,430,143
BAT-A/C#3			18,443,911
B/D Direct Dischargers			
BAT-B/D#1	109,252	23,230	22,610
BAT-B/D#2			45,152
BAT-B/D#3			45,204
A/C Indirect Dischargers			
PSES-A/C#1	90,181,808	33,181,762	38,331,249
PSES-A/C#2			50,981,759
PSES-A/C#3			51,807,047
B/D Indirect Dischargers			
PSES-B/D#1	7,424,870	1,934,646	4,378,836
PSES-B/D#2			4,990,451

Source: Section 308 Survey data and Radian Corp. estimates.

ASSESSMENT OF BENEFITS

This benefits assessment considers the human health, environmental, and economic benefits from reductions in effluent loadings and air emissions expected to result from the proposed rule. A variety of human health, environmental, and economic benefits might result from these reductions in effluent loadings and VOC emissions. In particular, the benefits assessment addresses the following benefit categories:

- Human health and agricultural benefits due to reductions in emissions of ozone precursors (i.e., reductions in VOC emissions)
- Human health benefits due to reductions in excess cancer risk
- Ecological and recreational benefits due to improved water quality
- Benefits from reductions in interference problems and improvements in worker health and safety at publicly owned treatment works (POTWs)
- Human health benefits due to reductions in systemic risk

Estimated benefits are monetized for the first two benefit categories, but the dollar magnitude of benefits for the three other benefit categories could not be quantified.

Benefits from VOC Emissions Reductions

The largest category of monetized benefits from the proposed guidelines results from reductions in ambient ozone concentrations due to reductions in VOC emissions. Controlling VOC emissions is beneficial because VOCs are precursors to ozone, which negatively affects human health and the environment. Studies have demonstrated that short-term exposure to elevated ozone concentrations results in acute effects on human health. Ozone also is believed to have chronic effects on human health. The annual human health benefits resulting from reductions in VOC emissions due to the proposed rule ranges from $27 thousand to $1.7 million in 1990 dollars ($31 thousand to $1.9 million 1994 $).

In addition to health effects, studies of the relationship between ambient ozone concentrations and greenhouse-controlled ozone concentrations and agricultural crop yields demonstrate that ozone negatively affects crop yields. Reductions in crop yields can in turn affect agricultural production, crop prices, and incomes of agricultural producers, and thus can affect social welfare. Thus, reductions in ozone concentrations that lead to improved crop yields will generate welfare benefits. Furthermore, ozone-induced crop yield changes can have secondary effects due to the responses of the agricultural community to the yield changes, including increased fertilizer and pesticide use, loss of wildlife habitat, increased soil erosion, and increased surface water and groundwater pollution. The annual agricultural-related economic welfare benefits from reductions in VOC emissions are estimated to range from $163 thousand to $276 thousand in 1990 dollars ($186 thousand to $315 thousand 1994 $).

Cancer Risk Reduction Benefits

The benefits from the proposed rule include human health benefits from reductions in excess cancer risk. These benefits result from reduced human exposure to carcinogenic contaminants through inhalation. The proposed regulations on the effluent discharges of pharmaceutical facilities are expected to remove many toxic substances that otherwise would volatilize and pose cancer risk to humans. Reductions in emissions of these carcinogens are expected to result in reductions in excess cancer risk in exposed populations. Based on the cancer risk assessment conducted for the RIA, the proposed guidelines are expected to result in 0.02 to 0.35 excess cancer cases avoided per year nationwide. The estimated value of the human health benefits from the cancer risk reductions associated with this rule ranges from $12 thousand to $4.7 million in 1990 dollars ($14 thousand to $5.4 million 1994 $) annually.

Human Health Benefits from Reductions in Noncarcinogenic Risk

Exposure to toxic substances poses risk of systemic and other effects to humans, including effects on the circulatory, respiratory or digestive systems and neurological and developmental

effects. The proposed rule might generate human health benefits by reducing exposure to these substances, thus reducing the risks of these associated effects.

Reductions in air emissions are expected to result in reduced systemic risk, with benefits ranging from reduced risk to zero to 126,000 individuals due to reduced exposure to two toxic pollutants. No systemic risk reductions are expected to result from reduced exposure to contaminated fish tissue or drinking water because estimated concentration levels under current conditions are below human health criteria or toxic effect levels. Sufficient data to quantify these benefits further are not available.

Ecological and Recreational Benefits due to Improved Water Quality

EPA expects the proposed effluent guidelines to generate environmental benefits by improving water quality. There are a wide range of benefits associated with the maintenance and improvement of water quality. These benefits include use values (e.g., recreational fishing), ecological values (e.g., provision of habitat), and passive use values. For example, water pollution might affect the quality of the fish and wildlife habitat provided by water resources, thus affecting the species using these resources. This in turn might affect the quality of recreational experiences of users, such as anglers fishing in the affected streams. In the RIA, EPA considers the value of the recreational benefits resulting from the proposed rule, but does not evaluate the other types of ecological and environmental benefits due to data limitations.

The projected reductions in toxic loadings to surface waters are significant. Pollutant loadings are estimated to decline by 57 percent, from 39.9 million pounds per year under current conditions to 17.1 million pounds per year under the proposed rule. The analysis comparing instream concentration levels to aquatic life water quality criteria estimates that current discharge loadings result in excursions of aquatic water quality criteria at two locations. The analysis also indicates that no excursions are expected to occur at these two sites under the proposed rule.

EPA estimates that the annual recreational benefits associated with the expected changes in water quality are on the order of thousands of dollars. EPA evaluates these recreational

benefits, applying a simple model that considers the change in consumer welfare likely to result from improved catch rates by recreational anglers at these two sites. EPA assumes that catch rates improve due to larger fish populations that are assumed to result from improved water quality.

Benefits from Reductions in Loadings Discharged to POTWs

The RIA considers three potential sources of benefits to POTWs from the proposed regulation: reductions in the likelihood of interference, pass through, and sewage sludge contamination problems; reductions in health and safety risks to POTW workers; and reductions in costs potentially incurred by POTWs in analyzing toxic pollutants and determining whether, and the appropriate level at which, to set local limits. Although the benefits from reducing these effects at POTWs might be substantial, the RIA does not quantify these benefits due to data limitations.

Toxic pollutants contained in the effluent loadings of pharmaceutical plants and discharged to POTWs might cause interference problems and/or pass through a POTW's treatment system and potentially affect water quality or contaminate sewage sludges. These problems might affect POTWs directly to the extent that they prevent POTWs from meeting their permits or sewage sludge criteria and they might affect surface water quality. The proposed rule is expected to help reduce these problems by reducing toxic loadings in the industry's effluent. Furthermore, the proposed rule might help to reduce shock releases (i.e., unexpected releases that contain high concentrations of toxic pollutants) from pharmaceutical facilities and thus reduce the likelihood that these releases will cause interference, passthrough and sewage sludge contamination problems at POTWs.

Anecdotal evidence from POTW responses to an EPA survey and analytic results indicate that such effects can occur. In addition, based on an analysis comparing POTW influent levels to available data on inhibition levels, inhibition problems are projected to occur at six POTWs for seven pollutants under current conditions. Inhibition problems are projected to occur at five

POTWs for three pollutants after the proposed rule. Sufficient data are not available to further quantify this benefit category.

Toxic substances in effluent discharges to POTWs pose health risks to POTW workers. For example, volatilization of toxics from POTW influent can pose a cancer risk to POTW workers or increase the risk of explosion at the plant. The proposed rule is expected to reduce these risks, thus generating human health benefits. Based on the assessment of the risk posed to POTW workers from exposure to toxic pollutants, the proposed rule is estimated to reduce occupational risk at six POTWs. Data are not available to monetize this benefit category.

Benefits from Reductions in Analytical Costs

In implementing local programs to control pollutants discharged to their systems, authorized POTWs often must set numerical limits on toxic loadings in discharges to the POTW, based on national categorical pretreatment standards or local limits determined by the POTW. In setting these local limits, POTWs sometimes need to undertake analyses to determine which pollutants warrant local limits and at what numerical level. Conducting these analyses is expensive, costing on the order of hundreds of thousands of dollars. Several POTWs contacted as part of EPA's survey of POTWs indicated that they will benefit from the establishment of national pretreatment standards by avoiding these analytical costs. In addition, they indicated that the pretreatment standards will bolster the legal authority of the limits they set.

Summary of Benefits

EPA estimates that the annual benefits resulting from the proposed rule will range from $202 thousand to $6.7 million in 1990 dollars ($231 thousand to $7.6 million 1994 $). Table ES-6 summarizes these benefits, by category. The range reflects the uncertainty in evaluating the effects of the proposed rule and in placing a dollar value on these effects. As indicated in the table, these benefits ranges do not reflect many of the benefit categories expected to result under the proposed rule, including human health benefits associated with potential reductions in

TABLE ES-6

POTENTIAL ECONOMIC BENEFITS FROM THE PROPOSED EFFLUENT GUIDELINES FOR THE PHARMACEUTICAL INDUSTRY

Benefit Category	Thousands of 1990 dollars per year
Reductions in Emissions of Ozone Precursors:*	
Human Health	$27 - $1,688
Agricultural	$163 - $276
Cancer Risk Reductions	$12 - $4,725
Environmental	Unknown
Avoidance of Interference Problems and Improvements in Worker Health and Safety at POTWs	Unknown
Systemic Risk Reductions	Unknown
Total	$202 - 6,689

*The estimates presented only include benefits associated with reductions in acute health effects and agricultural-related welfare benefits in nonattainment areas. Potential welfare benefits associated with forest yield, materials damage, and visibility are not addressed in this analysis.

chronic effects from ozone exposure, human health benefits associated with reductions in acute effects from ozone exposure in attainment areas, agricultural-related economic benefits from reductions in emissions of ozone precursors in attainment areas, ecological and recreational benefits from improvements in water quality, benefits from avoided interference and passthrough problems and improved worker health and safety at POTWs, and human health benefits from potential reductions in systemic risk. Therefore the reported benefit estimate understates the total benefits of the proposed rule.

COMPARISON OF COSTS TO BENEFITS

In this section, the estimate of the annual social costs of the regulation is compared to the estimate of the total annual benefits. Table ES-7 presents the annual benefits and annual costs of the proposed guideline in 1990 dollars. Benefits range from $202 thousand to $6.7 million ($231 thousand to $7.6 million 1994 $) annually. Costs total $108.4 million ($123.9 million 1994 $) annually.

TABLE ES-7

COMPARISON OF ANNUAL BENEFITS AND COSTS FOR THE PHARMACEUTICAL RULEMAKING (in thousands of 1990 dollars)

■ **Benefits**	
— Cancer risk reductions	$12 - $4,725
— Reductions in emissions of ozone precursors Human health Agricultural benefits	 $27 - $1,688 $163 - $276
— Total quantifiable benefits	$202 - $6,689
■ **Costs**	
Total Annual Costs to Industry	$70,000
Total Annual Social Costs	$108,400

SECTION ONE

INTRODUCTION

1.1 PURPOSE

This report has been prepared to comply with Executive Order 12866, which requires federal agencies to assess the costs and benefits of each significant rule they propose or promulgate. The regulations for the pharmaceutical industry, which are proposed by the U.S. Environmental Protection Agency (EPA, or the Agency), meet the Order's definition of a significant rule. The Agency has assessed both costs and benefits of the proposed rule, as presented in this Regulatory Impact Assessment (RIA).[1]

1.2 ORGANIZATION OF THE REPORT

The principal requirements of the Executive Order are that the Agency perform an analysis comparing the benefits of the regulation to the costs that the regulation imposes, that the Agency analyze alternative approaches to the rule, and that the need for the regulation be identified. Wherever possible, the costs and benefits of the rule are to be expressed in monetary terms. To address the analytical requirements of the Executive Order, this RIA is organized into seven major sections:

- Background
- Need for the Regulation
- Technology Options and Regulatory Alternatives
- Economic Impacts and Social Costs

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[1]The reader is referred to the Economic Impact Analysis (U.S. EPA, 1995b) for more detailed information on economic impacts, the profile of the pharmaceutical industry, and other sources of data.

- Pollutant Reduction
- Assessment of Benefits
- Comparison of Benefits to Costs

Section Two (Background) presents an overview of the pharmaceutical industry and describes the regulatory history of the proposed rulemaking.

Section Three (Need for the Regulation) briefly explains the marketplace failures that the proposed pollution control regulations are intended to correct. In addition, this section discusses the environmental factors necessitating the development of the rulemaking. Finally, the Agency's legal mandate for developing the regulation is summarized.

Section Four (Technology Options and Regulatory Alternatives) describes the options considered in the development of the proposed effluent guidelines and emission standards.

Section Five (Economic Impacts and Social Costs) presents the costs of compliance with the proposed regulations, the methodology and results of the economic impact analysis, and estimates of the social costs associated with the proposed effluent guidelines and emissions standards.

Section Six (Pollutant Reduction) presents proposed reductions in conventional and nonconventional constituents (including priority pollutants) released by the pharmaceutical industry. Estimates are based on current loading as reported by each survey respondent in the Section 308 Pharmaceutical Industry Survey. These loadings also are compared to independently estimated loadings generated through computer modeling.

Section Seven (Assessment of Benefits) presents qualitative and quantitative estimates of the human health and air and water quality benefits of the proposed rule.

Section Eight (Comparison of Benefits to Costs) compares annualized benefits and costs and discusses the context within which these results should be interpreted.

References are provided in Section Nine.

SECTION TWO

BACKGROUND

2.1 INDUSTRY OVERVIEW

This section presents a profile of the pharmaceutical industry that covers the statistical and descriptive information used to develop the methodology for the RIA. The profile includes an overview of the industry; a variety of statistics at the facility, owner company, and parent company level; and information on market structure and demand.

2.1.1 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.

2.1.2 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 would 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 by asset site groups facilities level from 1988 to 1990 ranged from approximately 5 percent to 7 percent. The median interest coverage ratios by asset size groups vary from approximately 464 percent to 2,043 percent. In addition, the profitability of the pharmaceutical industry appears to be above average among U.S. industries.

2.1.3 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. 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 obviously reduces 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 the RIA, however, the

conservative assumption that manufacturers cannot pass through compliance costs is used, except where impacts on consumers are analyzed (100 percent cost passthrough is assumed for this analysis).

2.2 REGULATORY HISTORY

2.2.1 The Clean Water Act—Background

The Clean Water Act (CWA), 33 U.S.C. 1251 et seq., 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 EPA is required to issue effluent limitations guidelines, pretreatment standards, and new source performance standards for "categories and classes of point sources" [Section 301(b)(2)(A)]. The Pharmaceutical Manufacturing Category is one such category. The Act calls for limitations to be based on Best Practicable Technology (BPT), Best Available Technology Economically Achievable (BAT), Best Conventional Pollutant Control Technology (BCT), New Source Performance Standards (NSPS), Pretreatment Standards for Existing Sources (PSES), and Pretreatment Standards for New Sources (PSNS).

The CWA establishes a BAT standard for the control of any of 65 "priority" (toxic) pollutants or classes of pollutants, as well as nonconventional pollutants directly discharged by an industrial category to navigable waters. In addition to considering economic achievability, the EPA, in assessing BAT, is to consider factors including the following: the age of the equipment and facilities involved, the process employed, process changes, and nonwater quality environmental impacts [Section 304(b)(2)(B)]. A BCT standard replaces BAT for the discharge of conventional pollutants from existing sources. Along with other factors specified in Section 304(b)(4)(B), the Act requires BCT limitations to be assessed in light of a two-part "cost-reasonableness" test. In addition, in setting new source performance standards, EPA is directed by Section 306 to consider, among other things, the cost of achieving effluent reductions.

Section 304(m) of the CWA, added by the Water Quality Act of 1987 (P.L. 100-4, February 4, 1987), requires EPA to review existing effluents limitations guidelines and standards

and to promulgate new or revised effluent guidelines and standards as necessary. On January 2, 1990, EPA published its Effluent Guidelines Plan in the *Federal Register* (55 FR 80) in which a schedule was established for the promulgation of effluent limitations guidelines and standards for several industry categories, including the pharmaceutical manufacturing industry.

2.2.2 Pharmaceutical Manufacturing Category

On October 27, 1983, EPA published final BPT, BAT, PSES, and NSPS limitations and standards for the Pharmaceutical Manufacturing Category (40 CFR Part 439). On December 16, 1986, EPA promulgated final BCT limitations essentially equivalent to the existing BPT limitations for this category. These final limitations and standards did not include any controls on the discharge of toxic volatile organic compounds (VOCs). On September 9, 1985 EPA stated in a *Federal Register* notice (50 FR 36638) that it was considering controls on the discharge of methylene chloride and other volatile VOCs from pharmaceutical point sources. In the 1986 Domestic Sewage Study (DSS) Report to Congress (EPA, 1986),[1] the Agency indicated that the Pharmaceutical Industry was a major source of hazardous pollutant discharges to the nation's Publicly Owned Treatment Works (POTWs). These discharges include both priority and nonconventional VOCs.

One of the recommendations of the DSS was that industry categories that were shown to be significant dischargers of hazardous waste to the nation's POTWs should undergo additional study. The purpose of these studies was to determine whether pretreatment standards controlling the discharge of hazardous pollutants should be promulgated for specific categories. As stated above, pharmaceutical manufacturing category was judged to be a major discharger of hazardous pollutants by the DSS. Consequently, the Industrial Technology Division (ITD) of EPA conducted a sampling and data gathering effort mainly among indirect discharging pharmaceutical manufacturing plants (some direct dischargers were also sampled) in order to obtain more information about hazardous pollutant discharges from pharmaceutical facilities and

[1]The study was conducted pursuant to the 1984 amendments to the Resource Conservation and Recovery Act (RCRA).

to determine if additional pretreatment standards designed to control the discharge of hazardous pollutants should be promulgated. The pharmaceutical sampling/study program was part of an overall effort known as the ITD/Resource Conservation and Recovery Act (RCRA) program and was carried out within ITD in response to the DSS.

The preliminary results of this study indicated that the pharmaceutical industry is indeed a major discharger of hazardous pollutants. Hence, as discussed in the last paragraph of Section 2.2.1, a schedule was established for the promulgation of effluent limitations guidelines and standards for the pharmaceutical manufacturing industry.

Prior to the data gathering for this regulation, EPA's last detailed information gathering effort involving the pharmaceutical industry occurred in 1978 and utilized a questionnaire that requested information about water use, wastewater characteristics, raw materials usage, treatment practices, and discharge status. The information obtained from the census was an essential part of the database used to promulgate the 1983 and 1986 regulations. However, in the course of conducting the recent ITD/RCRA sampling program, the Agency learned that the industry had changed in many respects since 1978, and much of their information was out of date.

EPA, therefore, conducted a new survey for this regulation. The Agency conducted its information collection activity via a two step process. The first step involved a screener questionnaire, which was sent to about 1,130 known pharmaceutical manufacturing facilities. This screener was administered in 1989 (OMB No. 2040-0124). The results of this screener were used to identify the pharmaceutical manufacturers that were to be a part of the second step, the Section 308 Pharmaceutical Survey, as discussed in the following section.

2.3 DATA SOURCES

The EIA (U.S. EPA 1995b), the basis of much of this RIA, 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 and Bradstreet (D&B), Robert Morris Associates

(RMA), the Pharmaceutical Manufacturers Association (PMA), and various journal articles. Most of the analysis conducted in Chapters 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 Chapter 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, as they are used to support the analyses in subsequent sections.

2.3.1 The Section 308 Pharmaceutical Survey

2.3.1.1 Background

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 manufacture active ingredients (subcategories A, B, C) and discharge process wastewater and formulating and mixing/compounding (subcategory D) facilities that have direct discharges or a

combination of direct and indirect discharges. EPA judged that a census of these facilities was necessary 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 which would make their effluent significantly different from other facilities in the same subcategory. Overall, EPA conducted a census of 202 facilities in these three 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 employee size based on 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* (1982). Overall, EPA sampled 42 pharmaceutical facilities in subcategories D and D/E. 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 sample weight of 2. All other censused facilities received a weight of 1. The coefficient of variation in any particular strata, i.e., employment size, is no greater than 15 percent. All subcategory D facilities are grouped with subcategory B facilities for the purpose of this analysis, which is discussed in Section Four.

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.

2.3.1.1 Uses of Survey Data

Certifying Facilities. All surveyed facilities were given the option to 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 surveyed facilities certified no significant economic impact and thus did not provide financial data.

Responding Firms and Facilities. The survey data from firms and reporting facilities 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.

2.3.2 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 major 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.

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.

SECTION THREE

NEED FOR REGULATION

Executive Order 12866 requires that the Agency identify the need for the regulation being proposed. The discharge of pollutants into effluent and hence into surface water and the emission of air pollutants pose a threat to human health and the environment. Risks from these emissions and discharges include increases in cancer risk, other adverse noncancer health effects on humans, and degradation of the environment. This section discusses: (1) the reasons the marketplace does not provide for adequate pollution control absent appropriate incentives or standards; (2) the environmental factors that indicate the need for additional pollution controls for this source category; and (3) the legal requirements that dictate the necessity for and timing of this regulation.

3.1 FAILURE OF MARKETS TO CONTROL POLLUTANTS

The need for effluent guidelines for this source category arises from the failure of the marketplace to provide the optimal level of pollution control desired by society. Correction of such a market failure can require federal regulation. The Office of Management and Budget defines market failures as the presence of externalities, natural monopolies, and inadequate information (U.S. Office of Management and Budget, 1989). This section addresses the category of externalities, which is the category of market failure most relevant to the general case of environmental pollution.

The concept of externalities partially explains the discrepancy between the supply of pollution control provided by owners and operators of pollution sources and the level of environmental quality desired by the general population. The case of environmental pollution can be classified as a negative externality because it is an unintended byproduct of production that creates undesirable effects on human health and the environment.

In making production decisions, owners and operators will only consider those costs and benefits that accrue to them personally (i.e., internalized costs and benefits). However, the cost of environmental pollution is not borne solely by the creators of the pollution because all individuals in the polluted area must share the social cost of exposure to the pollution, even if they had no part in creating the pollution. Therefore, although owners and operators might be the creators of pollution, they do not necessarily bear the full costs of the pollution. Government regulation is an attempt to internalize the costs of pollution.

If the people affected by a particular pollution source could negotiate with the party responsible for that source, the parties could negotiate among themselves to reach an economically efficient solution. The solution would be efficient because it would involve only those individuals who are affected by the pollution. In effect, the solution would involve the trading of pollution and compensation among the owner or operator and the people affected by the pollution.

Individual negotiation often does not occur in an unregulated market, however, because of high transactions costs, even if trade among the affected parties would be beneficial to all parties involved. For the majority of environmental pollution cases, the costs of identifying all the affected individuals and negotiating an agreement among those individuals is prohibitively high. Another problem preventing negotiations from taking place is that our current market system does not clearly define liability for the effects of pollution.

In the case of environmental quality, an additional problem is the public nature of this "good." Environmental quality is a public good because it is predominantly nonexcludable and nonrival. Individuals who willingly pay for reduced pollution cannot exclude others who have not paid from also enjoying the benefits of a less polluted environment. Because many environmental amenities are nonexcludable, individuals utilize but do not assume ownership of these goods, and therefore will not invest adequate resources in their protection. The result is that in the absence of government intervention, the free market will not provide public goods, such as a clean environment, at the optimal quantity and quality desired by the general public.

3.2 ENVIRONMENTAL FACTORS

In the case of the pharmaceutical industry, the result of the market's failure to promote water and air pollution control is that pollution of the nation's surface water, ground water, and air is not controlled to the optimal level. This industry releases significant amounts of pollutants to surface waters, wastewater treatment plants, wastewater treatment sludges, and air. Despite state and local regulatory programs, many areas are still adversely affected by pollutant discharges and emissions by this industry. Section Six discusses in detail water and air quality impacts of the regulations.

3.3 LEGAL REQUIREMENTS

The regulations are proposed under the authorities of Sections 301, 304, 306, 307, and 501 of the Clean Water Act (the Federal Water Pollution Control Act Amendment of 1972, 33 U.S.C. 1251 et seq., as amended by the Clean Water Act of 1987, Pub. L. 100-4, also referred to as the CWA or the Act) and under the authority of Section 112 of the Clean Air Act Amendments of 1990.

SECTION FOUR

TECHNOLOGY OPTIONS AND REGULATORY ALTERNATIVES

A number of alternatives are available to pharmaceutical facilities that would allow them to meet more stringent effluent limits. Key alternatives are advanced biological treatment and distillation. Other approaches include multimedia filtration, polishing ponds, cyanide destruction, granular activated carbon adsorption, pH adjustment/neutralization, and equalization. The following sections briefly describe these alternatives, all of which were considered by EPA for developing effluent guidelines for the pharmaceutical industry.

4.1 TECHNOLOGY COMPONENTS[1]

4.1.1 Advanced Biological Treatment

Advanced biological treatment is used in the pharmaceutical manufacturing industry to treat biochemical oxygen demand (BOD_5), chemical oxygen demand (COD), and total suspended solids (TSS) as well as to degrade various organic constituents. Among facilities with advanced biological treatment technologies that provide reduction of ammonia in the wastewater through nitrification, "best performance" has been defined as referring to systems that achieve, on a long-term basis, 90 percent BOD_5 reduction and 74 percent COD reduction in pharmaceutical manufacturing wastewater, under the existing BPT effluent limitations guidelines (40 CFR Part 439).

Biological systems can be divided into two basic types: aerobic (treatment takes place in the presence of oxygen) and anaerobic (treatment takes place in the absence of oxygen). According to the Section 308 Survey, only two pharmaceutical manufacturing facilities reported using anaerobic biological treatment systems. The four most common aerobic treatment

[1]This section is summarized from EPA's Development Document for this regulation (U.S. EPA, 1995a).

technologies in the industry are activated sludge, aerated lagoon, trickling filter, and rotating biological contactor (RBC).

In aerobic biological treatment processes, oxygen-requiring microorganisms decompose organic and nonmetallic inorganic constituents into carbon dioxide, water, nitrates, sulfates, organic byproducts, and cellular biomass. The microorganisms are maintained by adding oxygen and nutrients (usually nitrogen and phosphorus) to the system. Activated sludge and aerated lagoon processes are suspended-growth processes in which the microorganisms are maintained in suspension within the liquid being treated. The trickling filter and RBC processes are attached-growth processes in which microorganisms grow on an inert medium (e.g., rock, wood, plastic). Three types of activated sludge processes were listed as choices in the Section 308 Survey: single, two-stage, and oxygen-activated sludge. Table 4-1 shows that the majority of biological treatment systems used in the pharmaceutical industry involve the activated sludge approach.

An activated sludge treatment system normally consists of an equalization basin, a settling tank (primary clarifier), an aeration basin, a secondary clarifier, and a sludge recycle line. Sludge produced by these systems generally consists of biological waste products and expired microorganisms. Because the sludge can accumulate under certain operating conditions, periodic removal of sludge from the aeration basin might be necessary.

Generated sludge will require some type of storage, handling, and disposal. Biological sludges are normally treated in a two-step process prior to disposal: thickening followed by dewatering. Other sludge treatment can also be performed, but these two are the most significant processes. The goal for each of these operations is to decrease the overall volume of sludge.

Ammonia treatment by nitrification is achieved in biological treatment units by incorporating two additional sets of autotrophic microorganisms. The first set of microorganisms converts ammonia to nitrites and the second set converts nitrites to nitrates.

Some key design parameters for activated sludge systems include nutrient-to-microorganism ratio, mixed liquor suspended solids (MLSS), sludge retention time, oxygen

TABLE 4-1

SUMMARY OF MAJOR TREATMENT TECHNOLOGIES USED IN THE PHARMACEUTICAL MANUFACTURING INDUSTRY

Technology	Number of Facilities Using the Technology	
	Subcategory A/C	Subcategory B/D
pH Adjustment/Neutralization	81	45
Equalization	44	26
Biological Treatment		
Single-Stage Activated Sludge	31	21
Two-Stage Activated Sludge	2	2
Oxygen Activated Sludge	1	1
Aerated Lagoons	7	5
Trickling Filters	4	1
Rotating Biological Contactors	2	1
Multi-Media Filtration	3	3
Cyanide Destruction		
Alkaline Chlorination	6	0
H_20_2 Oxidation	3	0
Hydrolysis	1	0
Distillation Technologies		
Solvent Recovery		
Distillation	12	3
Distillation with reflux	28	5
Rectification	12	1
Wastewater treatment		
Steam stripping	4	0
Carbon Adsorption	6	4
Polishing Pond	2	6
Air Stripping	2	0

Source: Data based on responses from the 1990 Section 308 Survey (244 responding facilities).

requirements, nutrient requirements, sludge production, substrate removal rate constant (K), and percent BOD of effluent TSS.

4.1.2 Multimedia Filtration

Multimedia filtration is used in the pharmaceutical manufacturing industry to reduce TSS in wastewater. This technology also can be used to treat BOD in wastewater by removing particulate BOD. Multimedia filtration is performed by introducing a wastewater to a fixed bed of inert granular media. Suspended solids are removed from the wastewater by one or more of the following processes: straining, interception, impaction, sedimentation, and adsorption. This operation is continued until either solids "breakthrough" occurs (i.e., solids concentration increases to an unacceptable level in the discharge from the bed) or the head loss across the bed becomes too great (due to trapped solids) to operate the bed efficiently.

In multimedia filtration, a series of layers, each with a progressively smaller grain size medium (traveling from inflow to outflow of the bed), are used in the filtration bed. This design allows solids to penetrate deeper into the bed before becoming fixed, thus increasing the capacity of the bed and decreasing the buildup of head loss in the unit. Typical filtration media include garnet, crushed anthracite coal, resin beads, and sand. Though downflow (gravity flow) systems are the most common, upflow and biflow (influent is introduced above and below the filter medium, and the effluent discharges from the center of the filter medium) filtration units can also be used.

Some key design parameters associated with multimedia filtration units include wastewater flow rate, hydraulic loading rate, and filter medium depth.

4.1.3 Polishing Pond

Polishing ponds are used in the pharmaceutical manufacturing industry to remove TSS from wastewater using gravity settling. Some BOD removal associated with the settling of suspended solids can also occur.

The wastewater is introduced at one end of the pond and ultimately flows out the other end of the pond. The pond is designed such that the water retention time is high enough and the water is still enough to allow solids to fall out of suspension. If the flow is too fast or other mixing is added to the system, solids can be maintained in suspension and discharged from the pond.

To avoid anaerobic conditions in the bottom portion of the pond, these units must be designed to be shallow, which might require a large land area if flow to the unit is high. Depths of polishing ponds currently used in the industry range from 2.5 to 14 feet. Retention times range from 0.2 days to 14.6 days. In the past, polishing ponds have been designed with an earthen liner only; however, current regulations require installation of a minimum of two liners and a leak detection system (40 CFR 261.221) for most new applications. Polishing ponds will accumulate solids over time and therefore will require periodic cleanout.

4.1.4 Cyanide Destruction

Several cyanide destruction treatment technologies are currently used in the pharmaceutical manufacturing industry, including alkaline chlorination, hydrogen peroxide oxidation, and base hydrolysis. The alkaline chlorination treatment process involves reacting cyanide with elemental chlorine or hypochlorite to form nitrogen and carbon dioxide. The reaction is a two-step process and is normally performed separately in two reactor vessels. Because treatment is normally performed in batches, it is necessary to use an additional equalization tank to store accumulated wastewater during treatment. The reactors need to be equipped with agitators, and both reaction steps require close monitoring of pH and

oxidation/reduction potential (ORP). These reactions are normally performed at ambient temperatures.

Hydrogen peroxide treatment involves adding hydrogen peroxide to cyanide-bearing wastewater to convert free cyanide to ammonia and carbonate ions. This treatment is normally performed in batches in a reaction vessel or vessels. The treatment process consists of heating the wastewater to around 125°F and adjusting the pH in the reaction vessel to approximately 11. Hydrogen peroxide is added to the vessel and is allowed to react for approximately 1 hour.

Hydrolysis treatment involves reacting free cyanide with water under basic conditions to produce formate and ammonia. This process requires approximately 1 hour to proceed and is typically performed at a temperature between 170° and 250°C, and at a pH between 9 and 12.

4.1.5 Steam Stripping/Distillation

Steam stripping/distillation is used both in industrial chemical production (for chemical recovery and/or recycling) and in industrial waste treatment to remove gases and/or organic chemicals from wastewater streams by injecting steam into a tray or packed distillation column. In most cases, the organic components removed by steam stripping/distillation are water soluble. Steam stripping/distillation is an effective treatment for a wide range of aqueous streams containing organics and ammonia. Appropriately designed and operated distillation columns can treat a variety of waste streams ranging from wastewaters containing a single highly volatile constituent to complex organic/inorganic mixtures. Steam stripping/distillation can be used both as an in-plant process to recover concentrated organics from aqueous streams and as an end-of-pipe treatment to remove organics from wastewaters prior to discharge or recycle.

Steam stripping/distillation is usually conducted as a continuous operation in a packed tower or tray tower (sieve tray or bubble cap) with more than one stage of vapor-liquid contact. The wastewater enters near the top of the column and then flows downward by gravity, countercurrent to the steam, which is introduced at the bottom of the column. Steam can be either directly injected or reboiled, although direct injection is more common. The steam strips

volatile organics from the wastewater, which are then included in the upward vapor flow. As a result, the wastewater contains progressively less volatile organic compounds as it moves toward the bottom of the column. The extent of separation is governed by physical properties of the VOCs being stripped, the temperature and pressure at which the column is operated, and the arrangement and type of equipment used.

Steam stripping columns are used for stripping only and typically will not have any rectifying stages. Distillation columns can be used for stripping, rectification, or both. The difference between stripping columns and rectifying columns is the location of the feed stream. Stripping columns have a feed stream located near the top of the column while rectifying columns have a feed stream located near the bottom of the column. Pollutants that are phase-separated can usually be stripped from the wastewater in a steam stripper. Pollutants that are not phase-separable, such as methanol, will be more easily removed in a column with rectifying stages. Reflux, recycling of the overhead stream back to the column, can also be used to help pollutants which are difficult to strip to achieve a high concentration in the overhead steam.

The ancillary equipment used in conjunction with steam stripping/distillation columns includes a condenser and subcooler, pumps for the feed and reflux streams, a feed preheater and bottoms cooler, a decanter, a storage tank, and an air pollution control device to contain any vapors from the condenser.

The majority of pharmaceutical manufacturing facilities that currently use steam stripping/distillation columns to treat their wastewater use stainless steel. Salts and other pollutants can contribute to scaling and corrosion inside the column. Thus, timely maintenance and adequate labor should be provided to deter scaling problems.

The key design parameters for steam stripping/distillation columns are the steam-to-feed ratio and the number of trays or equilibrium stages in packed columns. These parameters are determined by the equilibrium ratio of the least strippable contaminant in the wastewater stream and the removal efficiency required to treat the contaminant to the desired concentration.

4.1.6 Granular Activated Carbon Adsorption

Granular activated carbon (GAC) adsorption is used in the pharmaceutical manufacturing industry to treat BOD, COD, or organic constituents in wastewater. Adsorption is a process in which soluble or suspended materials in water are bonded onto the surface of a solid medium. Activated carbon is an excellent medium for this process because of its high internal surface area, high attraction to most adsorbates (i.e., the constituents to be treated), and the fact that it is hydrophobic (i.e., water will not occupy bonding sites and interfere with the adsorption process). Constituents in the wastewater bond onto the GAC grains until all surface bonding sites are occupied. At this point the carbon is considered to be "spent," and it requires regeneration, cleaning, or disposal.

Activated carbon is normally produced in two standard grain sizes: powdered activated carbon (PAC) with diameters less than a 200 mesh, and GAC with diameters greater than 0.1 mm. PAC is generally added to the wastewater, whereas GAC is normally used in flow-through fixed-bed units.

For treatment units, GAC is packed into one or more beds or columns. Multiple beds are more common and are normally operated in series because this design allows for monitoring between beds, and therefore minimizes the risk of discharging wastewater from the system with concentrations above acceptable levels. Wastewater flows through a bed and is allowed to come in contact with all portions of the GAC. The GAC in the upper layers of the bed is spent first as bonding sites are occupied, and the GAC in progressively lower regions is spent over time as the adsorption zone moves down through the unit. When contaminant concentrations at the bottom of the bed begin to increase above acceptable levels, the bed is considered to be spent and must be removed. This description assumes that beds are operated in downflow mode; however, it is also possible to use an upflow design for GAC systems.

Once a bed is spent, the carbon can be treated in three ways: regeneration, backwash, or disposal. Normally, it is possible to use high heat (1,500 to 1,700° F), steam, or chemical treatment to regenerate the spent carbon.

The performance of GAC treatment units can be affected by several factors. Three important design criteria are saturation loading, wastewater TSS concentration, and hydraulic loading.

4.1.7 pH Adjustment/Neutralization

Because many treatment technologies used in the pharmaceutical manufacturing industry are sensitive to pH fluctuations, pH adjustment, or neutralization, can be required as a part of an effective treatment system. A pH adjustment system normally consists of a small tank (10 to 30 minutes retention time) with mixing and a chemical addition system. To adjust pH to a desired value, either acids or caustics can be added in the mixing tank. Some treatment technologies require a high or low pH to effectively perform treatment (e.g., air stripping of ammonia requires a pH around 10 or 11). pH is generally adjusted to between 6 and 9 prior to final discharge.

4.1.8 Equalization

Because many of the treatment technologies listed in this section are performed continuously and some are sensitive to spikes of high flow or high contaminant concentrations, it is necessary to include equalization as a part of most treatment systems. Equalization is normally performed in large tanks or basins designed to hold a certain percentage of a facility's daily wastewater flow. Equalization will equalize high- and low-flow portions of a typical production day by allowing wastewater to be discharged to downstream treatment operations at a constant flow rate. Equalization can provide a continuous wastewater feed to operations such as biological treatment that perform more effectively under continuous load conditions.

The mixing that occurs in an equalization basin will help to minimize spikes of various contaminants in the discharged wastewater. This equalization will prevent loss of treatment effectiveness or treatment system failures associated with these spikes.

4.2 SUMMARY OF REGULATORY ALTERNATIVES

EPA has developed a set of regulatory options, which 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 BPT, BCT, BAT, and NSPS options; for indirect dischargers, PSES and PSNS technology options are examined.

Table 4-2 presents the 37 regulatory options considered by EPA and defines the technologies associated with each option. 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 selected for nonconventional pollutants.
- For direct discharging B/D facilities, BPT-B/D#2 is selected for conventional pollutants and BAT-B/D#1 is selected 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#2 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.

TABLE 4-2

REGULATORY OPTIONS CONSIDERED IN THE REGULATORY 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 4-2 (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, 1995a), 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.

SECTION FIVE

ECONOMIC IMPACTS AND SOCIAL COSTS

The Agency evaluates the costs and economic impacts of pollution control standards in order to assess the potential impact of the standards on the nation's economy in terms of facility closures, job losses, and market disruptions. These impacts can be translated into measures of the social cost of the regulation, which is the monetary value of these disturbances. This information, compared to the potential benefits of the proposed standards, is useful for policy decisions concerning the stringency of the standard.

5.1 REGULATORY COMPLIANCE COSTS

The regulatory compliance costs considered in this section do not represent full social costs. Instead, they represent the costs that will be experienced by the regulated industry. Section 5.4 discusses social costs, including costs to the federal government for providing tax subsidies for pollution control equipment.

EPA used a cost annualization model to estimate the annual compliance cost for each pharmaceutical facility of pollution control equipment and operations needed to meet the regulation[1]. This model provides the data necessary for a 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 on corporate income tax filings), 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.

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[1]Note that some facilities incur no costs for certain options because EPA has determined their current pollution control systems meet the regulatory requirements of those options.

The annualized costs for all regulatory options for direct dischargers are given in Tables 5-1 and 5-2. The average annualized costs per facility for BPT options range from $0 to $764,975 for A/C facilities and $0 to $54,346 for B/D facilities. The aggregate annualized costs for BPT options range from $0 to $18.4 million for A/C facilities and $0 to $0.8 million for B/D facilities. For BCT options, the average annualized costs per facility range from $147,972 to $637,021 for A/C facilities and $22,888 to $51,047 for B/D facilities. For these same facility types, the aggregate annualized costs for BCT options range from $3.6 million to $15.3 million and from $0.3 million to $0.7 million, respectively. For the BAT options, the average annualized costs per facility range from $274,188 to $3,172,654 for A/C facilities and $50,626 to $206,634 for B/D facilities. The aggregate annualized costs for these facilities range from $6.6 million to $76.1 million and $0.7 million to $2.9 million, respectively.

The annualized costs for regulatory options for indirect dischargers are given in Table 5-3. For A/C facilities, the average annualized costs per facility of the PSES options range from $392,782 to $1,398,273. The aggregate annualized costs for these facilities range from $34.6 million to $123.0 million. For B/D facilities, the average annualized costs per facility of the PSES options range from $51,778 to $414,791. The aggregate annualized costs for these facilities range from $7.9 million to $63.5 million.

The annualized costs for the selected options for this proposed rulemaking are shown in Table 5-4. The average annualized costs per facility for the selected options are $1.1 million for BAT-A/C#2, $50,626 for BAT-B/D#1, $0.4 million for PSES-A/C#1, and $51,778 for PSES-B/D#1. The aggregate annualized costs are $26.8 million for BAT-A/C#2, $0.7 million for BAT-B/D#1, $34.6 million for PSES-A/C#1, and $7.9 million for PSES-B/D#1, for a total aggregate cost of $70.0 million.

5.2 ECONOMIC IMPACT ANALYSIS METHODOLOGY

EPA performed several analyses to determine the economic impacts of the proposed effluent guidelines for pharmaceutical facilities. These analyses included a facility-level analysis, an owner company-level analysis, an employment and community-level analysis, a foreign trade

TABLE 5-1

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 5-2

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 5-3

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 5-4

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

* The cost of BAT options include the costs of meeting the selected BPT options.
** 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.

impact analysis, a regulatory flexibility analysis, a distributional analysis, and an analysis of the impacts of the guidelines on new sources. The methodologies for these analyses are described below.

5.2.1 Facility-Level Analysis Methodology

The facility-level analysis identified facilities that are likely to close as a result of incremental compliance costs. In the facility-level analysis, the 65 facilities that certified in the Section 308 Pharmaceutical Survey that the regulation would not affect them were automatically placed in the "no closure" category of the model. These 65 facilities represent 72 facilities in the survey universe. The 76 firms operating only as one facility, i.e., owner-operated facilities or "firm/facilities," were counted in this analysis, but were assumed to pass through this analysis without closing. Impacts on these firm/facilities were measured in the company-level analysis. The facility closure model evaluated the remaining 134 of the 282 facilities in the survey universe. Facility closures were 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 was greater than what the facility is expected to generate in earnings, then it was assumed that the owner would liquidate the facility. Salvage value includes the value of current (i.e., short-term) assets and fixed (i.e., long-term) assets. Data for the facility-level analysis was either taken directly from the Section 308 Survey or estimated based on data that was provided by other facilities.

5.2.2 Owner Company-Level Analysis Methodology

The company-level analysis evaluated the effects of regulatory compliance on companies owning one or more affected pharmaceutical manufacturing facilities and identified other impacts not captured in the facility analysis. The analysis assessed 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 were assessed using ratio analysis, which employs two indicators of financial viability: the rate of return on assets (ROA) and the interest coverage ratio (ICR). 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. Data from the Section 308 Survey and engineering costs analyses were used to calculate baseline and postcompliance ROAs and ICRs.

In the baseline ratio analysis, the company's financial viability before the investment was evaluated. ROA and ICR were computed with the survey data. To evaluate the baseline viability of the companies analyzed, the baseline ROA and ICR values were 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 was less than the first quartile value from Robert Morris Associates (RMA) and Dun & Bradstreet (D&B) were judged to be vulnerable to financial failure regardless of compliance costs.

In the postcompliance analysis, the company's financial condition subsequent to the investment was predicted. The relevant survey data (net income, EBIT [net income and earnings before interest and taxes], total assets, and interest expenses) were adjusted to reflect annual compliance costs estimated at the facility level as well as losses in income caused by facility closures, if any. The standard postcompliance analysis, referred to as Postcompliance Analysis 1, evaluated impacts on companies that were not found to be vulnerable in the baseline analysis. For these healthier companies, if either of the postcompliance ROA and ICR values fell below the quartile benchmarks, then the company was judged to be vulnerable to financial failure as a consequence of regulatory compliance; these companies were determined to sustain a "significant impact" as a result of the regulation.

Postcompliance Analysis 1 incorporates EPA's standard methodology for judging impact. Because of EPA's concerns that pharmaceutical industry investors are more tolerant of extended periods of loss during product development phases, two additional analyses investigating firms that are projected to fall in the baseline case have been undertaken. These two analyses are discussed below as Postcompliance Analysis 2 and 3. These analyses are presented as sensitivity analyses.

Postcompliance Analysis 2 examined the relative percentage change in ROA or ICR as a result of compliance costs or facility closures for firms that have positive net income and/or EBIT, but whose ROA or ICR fall below benchmarks that is the firm is considered a baseline failure. This analysis determined 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 was considered a major impact.

Postcompliance Analysis 3 evaluated firms with negative ROA or ICR ratios that were projected to fail in the baseline case. Although changes in ROA or ICR ratios that already are negative are difficult to present meaningfully, the proportion of the post-compliance net income or EBIT loss attributable to compliance costs provided a qualitative sense of impact. As in Postcompliance Analysis 2, a change of more than 5 percent was considered a major impact.

When changes in ROA, ICR, or net income among these firms in postcompliance Analysis 2 and 3 exceeded 5 percent, the firms in question were evaluated in more detail to determine if any unusual circumstances might indicate they were not likely to fail in the baseline.

Finally, the Profitability Analysis determined impacts on profitability among firms estimated to have no significant impact from compliance costs in postcompliance Analysis 1. This analysis investigated the percentage change in ROA among the healthy firms to assess impacts on profitability. Again, a change of more than 5 percent was considered a major impact.

5.2.3 Employment and Community-Level Analysis Methodology

The employment loss and community-level impact analysis investigated employment losses and resulting community-level impacts from compliance with the effluent guidelines. Primary employment losses are those losses occurring only within the pharmaceutical manufacturing industry and stem from facility closures and firm failures. Secondary impacts include employment losses in other industries that provide input to the pharmaceutical manufacturing process and other supporting industries and are based on the use of a multiplier. Primary and secondary employment losses were summed to obtain the total impact on community

employment levels resulting from implementation of the effluent guidelines. A change in the community employment rate of more than 1 percent is considered major.

Employment losses are offset to some extent by the need to hire workers to manufacture, install, and maintain the pollution control equipment. Direct employment effects associated with the manufacture, installation, and operation of the pharmaceutical industry compliance equipment were estimated. Then the additional employment effects that might occur through the indirect and induced effect mechanisms (secondary effects) were considered, using a range of multipliers. Primary and secondary employment losses were then subtracted to produce the net gain or loss associated with the proposed effluent guideline.

5.2.4 Foreign Trade Impact Analysis Methodology

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, EPA conducted a foreign trade impact analysis. Using data from the Section 308 Survey, the value of 1990 pharmaceutical exports was estimated for facilities expected to close. These values were summed across facilities to obtain an estimate of the total value of U.S. pharmaceutical exports that would no longer be produced. This value was then compared to the total value of U.S. pharmaceutical exports produced in 1990.

5.2.5 Regulatory Flexibility Analysis Methodology

EPA conducted a regulatory flexibility analysis to ensure that small entities potentially affected by the new effluent guidelines will not be disproportionately burdened by the regulation. The affected population of small businesses was defined and estimated. For simplicity, the regulatory flexibility analysis defined all pharmaceutical firms as small if they employ fewer than 750 persons. Impacts stemming from recordkeeping and reporting requirements and from significant alternatives to the proposed rule are discussed. Finally, firm failures and impacts on

profitability and the present value of net income among small firms resulting from the selected regulatory options are discussed by size category and compared to impacts among large firms to determine if small firms are disproportionately affected by the proposed effluent guidelines.

5.2.6 Distributional Analysis Methodology

For the distributional analysis, the zero cost passthrough assumption used in the other analyses was not used. Instead, it was assumed that manufacturers will raise pharmaceutical prices in response to increased regulatory costs. To determine upper bound impacts, it was further assumed that all cost increases can be passed through to consumers. The extent to which drug prices can rise assuming perfectly inelastic demand was determined as the ratio of total compliance costs to total cost of pharmaceutical production in the affected facilities. First, the extent to which drug prices could rise was determined as the ratio of total compliance costs to total cost of pharmaceutical production in the affected facilities. The analysis then investigated the impacts of increased drug prices on various demographic groups, looking at a sampling of products among some of the more highly affected facilities (those facilities where compliance costs as a proportion of total costs of production are greater than 10 percent) to determine their likely consumers.

5.2.7 New Source Analysis Methodology

The methodology for analyzing impacts on new sources extrapolates qualitatively from impacts on existing sources to those on new sources (see Section 5.3.7). NSPS and PSNS options are more stringent than BAT options. Thus, the difference in cost to an average facility to meet the more stringent requirements is compared to average total and pharmaceutical manufacturing costs. If the cost difference is less than 1 percent of pharmaceutical manufacturing cost, barriers to entry are considered negligible.

5.3 ECONOMIC IMPACT ANALYSIS RESULTS

The results for the facility-level analysis, owner company-level analysis, employment and community-level analysis, foreign trade impact analysis, regulatory flexibility analysis, distributional analysis, and the analysis on the impacts of the guidelines on new sources are presented below. As in Section 5.1, the regulatory compliance costs considered in this section do not represent full social costs, which are discussed in Section 5.4.

5.3.1 Facility-Level Analysis Results

The baseline facility-level analysis indicated that 38 facilities, or 13 percent of the total number of facilities, will close in the baseline. These facilities projected to close in the baseline case are not owner-operated facilities. The postcompliance analysis predicts that no facilities will close as a result of the selected regulatory options, although one A/C direct facility and one B/D indirect facility are estimated to close under the most stringent options for these two groups of facilities.

5.3.2 Owner Company-Level Analysis Results

The baseline analysis indicated that out of 187 firms, 54, or 29 percent, are likely to fail even before the impact of the effluent guideline requirements are considered. The results of Postcompliance Analysis 1 are presented in Table 5-5. Postcompliance Analysis 1 indicates that under the selected regulatory options only two firms with A/C indirect discharging facilities and one firm/facility, a B/D indirect discharger, are expected to experience significant impacts as a result of compliance costs. Overall, these firms represent 2.3 percent of all regulated firms that do not fail in the baseline.

The results of the Postcompliance Analysis 2, which are presented in Table 5-6, indicate that a total of nine firms, or about 31 percent of marginal firms with positive EBIT, are expected to incur substantial impacts (i.e., greater than 5 percent change in ICR) if they do not fail for

TABLE 5-5

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%	0.7%
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 5-6

POSTCOMPLIANCE ANALYSIS 2
(FIRMS PROJECTED TO FAIL IN THE BASELINE ANALYSIS)

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 5-7

** 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 5-7

Source: ERG estimates.

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

The Postcompliance Analysis 3 results, which are presented in Table 5-7, indicate that six firms with negative EBIT (24 percent) 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) with negative net income are expected to incur substantial impacts if they do not fail for other reasons.

The more in-depth analysis of the viability of these firms noted as potentially highly affected in the post-compliance analysis if they do not fail in the baseline revealed that there appeared to be no unusual circumstances that might indicate these firms would not fail, with one exception. The one firm that might not fail showed unusually strong growth over the 3-year survey period. However, when only 1990 data were used (i.e., it is assumed that 1990 data are more representative of future health than the 3-year average), this firm was shown to be able to absorb the compliance costs without undue effect on ROA or ICR. Thus the initial Postcompliance Analysis 1 is considered a reliable estimate of postcompliance impact.

Table 5-8 presents results from the Profitability Analysis, which indicated that 15 firms (15 percent of all firms in the analysis) will have significant impacts on returns, although only one firm will have impacts of greater than 50 percent decline on returns. When the firms that certified that they would experience no impacts from any effluent guideline also were considered, only 11 percent of firms in the postcompliance analysis were considered likely to experience major impacts short of firm failure. Note that this impact would be less if it was assumed that firms could pass through some of their compliance costs in the form of higher prices. It is also useful to note that median ROA of this group is quite high and thus many of these firms could sustain this level of impact while still showing adequate to good returns.

TABLE 5-7

POSTCOMPLIANCE ANALYSIS 3
(FIRMS PROJECTED TO FAIL IN THE BASELINE ANALYSIS)

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.

TABLE 5-8

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.

5.3.3 Community-Level Analysis Results

The baseline impacts from the analysis on primary employment before any compliance costs are incurred total 14,381 jobs estimated to be lost, out of a total employment of 147,804 workers[2] (9.7 percent of total employment). 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.

No employment losses were projected to occur as a result of regulatory options for direct dischargers. For indirect dischargers, however, total projected primary employment losses resulting from the selected regulatory options were 78 full-time equivalent (FTE) positions among A/C indirects and 13 FTEs among B/D indirects, for a total of 91 FTEs or 0.07 percent of total employment for the affected portion of the industry. Secondary losses were predicted to be 541 FTEs.

None of these losses is expected to result in a change of employment rates of more than 1 percent in the affected communities.

The sum of primary and secondary employment gains is calculated to range from 218 FTEs to 2,890 FTEs. Net gains and losses thus range from a loss of 323 FTEs to a gain of 2,349 FTEs.

5.3.4 Foreign Trade Impact Analysis Results

The impact of effluent guidelines on pharmaceutical exports and the U.S. balance of trade was found to be negligible. The one firm/facility predicted to close as a result of the effluent guidelines has pharmaceutical exports totaling $0.08 million. The loss of these exports

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

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.

5.3.5 Regulatory Flexibility Analysis Results

Small firms make up 76 percent of the 190 firms in the survey universe. The largest percentage of firms are in the 100-499 employees size group (37 percent of all firms in the survey universe).

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. Monitoring costs total $9.0 million annually and are 15 percent of the total annual compliance cost for the selected options. Large firms incur the largest proportion of monitoring costs (61 percent of total monitoring costs).

No significant alternatives to the proposed rule will substantially reduce impacts on small entities, thus the Agency believes the stated objectives of the Clean Water Act are met with this proposed rule and the impacts to small firms have been considered, where possible.

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, although only 2 percent of small firms in the postcompliance analysis are affected in this manner. In addition, 14 of 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. Note, however, that impacts would be less if firms can pass through some of their compliance costs. Also, even though returns drop substantially, the median baseline ROA in this group is quite high.

When cash flow is analyzed, impacts seem less disproportionate. Except in the smallest size category (0 to 18 employees) the total present value of compliance costs as a percentage of

the present value of net income is smaller among small firms than among large firms. Over all firms, the present value of compliance costs is less than 1 percent of the present value of net income.

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 smaller, on average, among small firms than among large firms; thus, impacts to small firms are not expected to be disproportionate to those for large firms.

5.3.6 Distributional Analysis Results

For all the selected regulatory options, the ratio of compliance costs to total pharmaceutical costs averaged 1.6 percent. Most facilities would incur compliance costs less than 1 percent of total pharmaceutical costs. Only three facilities (2 percent of all facilities) would incur compliance costs greater than 10 percent of total pharmaceutical costs.

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. It was further determined that individuals 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. These groups include Hispanics, young adults, African Americans, young children, and the elderly. Thus, 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), impacts on mass consumers of drugs such as HMOs, governments, and, indirectly, third-party insurers should be minimal.

5.3.7 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 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.

5.4 SOCIAL COSTS OF REGULATION

Costs reported earlier in this section are those imposed on industry. However, these costs are reduced by the tax savings realized by industry because of depreciation allowances on the capital and operating expenditures for the applicable pollution control equipment. Thus these costs do not reflect the true social costs of installing and operating the equipment. A major component of social cost is the cost to government of providing these tax savings to industry.

In addition to compliance costs and costs to government for depreciation allowances, other monetary and nonmonetary outlays are made by government. Government administrative costs and costs of reallocating displaced workers are two additional monetary costs. Nonmonetary costs include losses in consumers' or producers' surpluses in product markets, discomfort or inconvenience, loss of time, and slowing the rate of innovation. The social costs estimated here, therefore, are a very large portion of, but not the true total social cost of the proposed regulation. The costs reported here are thus only a close estimate of this true cost.

To model the social costs, the entire annual *pre-tax* cost of the proposed effluent guideline is estimated, using the same time period (16 years) and the discount rate advocated by OMB as appropriate for annualizing social costs of 7 percent (rather than the higher-average discount rate of 11.4 percent reported by Section 308 respondents).

The estimated social costs of the proposed regulation are shown in Tables 5-9 to 5-12. Tables 5-9, 5-10, and 5-11 present an estimate of the social costs of regulating the A/C direct discharges, B/D direct dischargers, and the indirect dischargers, respectively, by option and are reported in 1990 dollars. Aggregate annualized costs range from $0 per year to $28.1 million per year for BPT options for A/C direct discharges and from $0 to $1.1 million for B/D direct dischargers. Aggregate annualized costs of BAT options range from $10.1 million to $124.1 million for A/C direct dischargers and range from $1.2 million to $4.1 million for B/D direct dischargers. Aggregate annualized costs for PSES options for A/C indirect dischargers range from $53.9 million to $197.4 million, while for B/D indirect dischargers they range from $11.6 million to $104.7 million. The estimate of total annual social costs for all selected options is

TABLE 5-9

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

Option Number	Total Capital Costs	Total O&M Costs	Total Pretax 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	$8,607,496	$358,646
BPT-A/C#3	$21,891,929	$7,488,423	$9,805,851	$408,577
BPT-A/C#4	$37,455,760	$21,764,186	$25,729,165	$1,072,049
BPT-A/C#5	$44,204,216	$23,420,779	$28,100,133	$1,170,839
BCT Option Costs				
BCT-A/C#1	$16,875,845	$2,957,486	$4,743,924	$197,663
BCT-A/C#2	$32,439,676	$16,545,942	$19,979,929	$832,497
BCT-A/C#3	$39,188,132	$19,054,074	$23,202,438	$966,768
BAT Option Costs				
BAT-A/C#1	$15,050,112	$8,544,621	$10,137,790	$422,408
BAT-A/C#2	$56,392,127	$35,689,088	$41,658,626	$1,735,776
BAT-A/C#3	$68,035,029	$57,980,678	$65,182,706	$2,715,946
BAT-A/C#4	$92,851,663	$114,229,651	$124,058,709	$5,169,113

*Total Pretax 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. estimates of capital and operating costs for pollution control equipment.

TABLE 5-10

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

Option Number	Total Capital Costs	Total O&M Costs	Total Pretax 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	$583,467	$41,676
BPT-B/D#3	$2,976,515	$754,333	$1,069,420	$76,387
BCT Option Costs				
BCT-B/D#1	$559,015	$448,905	$508,081	$36,292
BCT-B/D#2	$2,929,830	$683,889	$994,034	$71,002
BAT Option Costs				
BAT-B/D#1	$644,446	$1,104,801	$1,173,021	$83,787
BAT-B/D#2	$1,741,330	$937,108	$1,121,441	$80,103
BAT-B/D#3	$3,002,607	$1,950,161	$2,268,010	$162,001
BAT-B/D#4	$10,310,180	$3,058,423	$4,149,835	$296,417

*Total Pretax 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. estimates of capital and operating costs for pollution control equipment.

TABLE 5-11

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

Option Number	Total Capital Costs	Total O&M Costs	Total Pretax Annualized Costs	Average Annual Cost per Facility*
A/C Facilities				
PSES-A/C#1	$70,795,915	$46,441,499	$53,935,789	$612,907
PSES-A/C#2	$90,082,486	$81,860,584	$91,396,504	$1,038,597
PSES-A/C#3	$143,989,655	$105,781,635	$121,024,041	$1,375,273
PSES-A/C#4	$186,990,945	$177,615,256	$197,409,678	$2,243,292
B/D Facilities				
PSES-B/D#1	$25,160,649	$8,956,179	$11,619,626	$75,945
PSES-B/D#2	$30,429,899	$16,986,223	$20,207,461	$132,075
PSES-B/D#3	$61,970,107	$98,119,347	$104,679,357	$684,179

*Total Pretax 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. estimates of capital and operating costs for pollution control equipment.

TABLE 5-12

COMPLIANCE COSTS FOR SELECTED REGULATORY OPTIONS (1990 $)

Option Number	Total Capital Costs	Total O&M Costs	Total Pretax Annualized Costs	Average Annual Cost per Facility*
BAT-A/C#2	$56,392,127	$35,689,088	$41,658,626	$1,735,776
BAT-B/D#1	$644,446	$1,104,801	$1,173,021	$83,787
PSES-A/C#1	$70,795,915	$46,441,499	$53,935,789	$612,907
PSES-B/D#1	$25,160,649	$8,956,179	$11,619,626	$75,945
Total**	$152,993,137	$92,191,568	$108,387,062	$388,484

* Total Pretax 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. estimates of capital and operating costs for pollution control equipment.

shown in Table 5-12. Total social costs resulting from the proposed effluent guideline are estimated to be $108.4 million per year.

SECTION SIX

POLLUTION REDUCTION

6.1 ESTIMATES OF REDUCTIONS IN POLLUTANTS BASED ON THE SECTION 308 SURVEY

EPA has established final raw, current, and proposed loadings for nonconventional constituents that currently are candidates for regulation in the pharmaceutical industry and for which treatment data are available or a data transfer could be performed to develop proposed long-term mean (LTM) effluent concentrations. In establishing these loadings, EPA relied on preliminary loadings developed for conventional and nonconventional pollutants in the pharmaceutical industry. For the organic constituents given preliminary consideration, available data were insufficient to develop proposed loadings. Raw, current, and proposed loadings for the conventional pollutants' BOD and TSS and the nonconventional pollutants' COD have not changed from the earlier assessment and therefore are not included here.

This section summarizes the methodologies used and assumptions made to develop final loadings for the nonconventional pollutants that are candidates for regulation. EPA calculated these final loadings using data from the Section 308 Survey database and Radian's WATER.DBF, STEAM.DBF, and AIR.DBF treatability databases, as well as some results derived using a computer model, WATER7. More information on the methods used for estimating water and air pollutant reductions can be found in the Development Document (EPA, 1995a).

Table 6-1 presents the loadings and reduction estimates by type of facility (i.e., A/C direct, B/D direct, A/C indirect, and B/D indirect). Section 6.2 describes how WATER7 estimates were derived. Note that WATER7 estimates were derived for both water and air emissions but the loads and reductions calculated and used in this RIA are estimated using WATER7 for air emissions only. The Section 308 survey was used to calculate water loads and reductions.

TABLE 6-1

ESTIMATED POLLUTANT LOADINGS BY TYPE OF FACILITY

Regulatory Option	Raw Load (lb)	Current Load (lb)	Total Load Reduction (lb)
A/C Direct Dischargers			
BAT-A/C#1	77,906,785	5,133,649	4,894,776
BAT-A/C#2			18,430,143
BAT-A/C#3			18,443,911
B/D Direct Dischargers			
BAT-B/D#1	109,252	23,230	22,610
BAT-B/D#2			45,152
BAT-B/D#3			45,204
A/C Indirect Dischargers			
PSES-A/C#1	90,181,808	33,181,762	38,331,249
PSES-A/C#2			50,981,759
PSES-A/C#3			51,807,047
B/D Indirect Dischargers			
PSES-B/D#1	7,424,870	1,934,646	4,378,836
PSES-B/D#2			4,990,451

Source: Section 308 Survey data and Radian Corp. estimates.

6.2 ESTIMATES OF REDUCTIONS IN POLLUTANTS BASED ON THE WATER7 MODEL

6.2.1 Introduction

As noted above, the Section 308 Survey requested information from facilities on the fate of raw chemicals used in their manufacturing processes. Table 3-2 of the survey requested from each facility an estimate of the quantity of raw materials going into product, emitted into air as in-plant fugitive emissions, emitted into air from wastewater collection and treatment, degraded or destroyed, discharged in wastewater, and otherwise disposed. After reviewing these quantities, the Agency questioned the pollutant loads reported as emitted to air from wastewater, biodegraded or destroyed, and discharged in wastewater. Because the Agency believes that more air emissions are occurring from these facilities than were reported, it developed an independent estimate of these loadings using the EPA's Office of Air Quality Planning and Standards (OAQPS) WATER7 model.

EPA's estimate of the fate of organic loads was performed using raw wastewater pollutant load and treatment unit data from the detailed survey questionnaires collected from 244 pharmaceutical manufacturing facilities. The Agency used the total loading for pollutants emitted to air from wastewater collection and treatment, degraded or destroyed, and discharged in wastewater as an estimate of the raw wastewater loading. The disposition of this raw loading from the survey responses was compared to the disposition estimated using the WATER7 computer model.

Section 6.2.2 provides a brief description of the WATER7 model and Section 6.2.3 discusses the methodology followed in performing the WATER7 analysis.

6.2.2 WATER7 Model Description

The WATER7 model evaluates several pollutant pathways including volatilization, biodegradation, and adsorption onto solids for individual waste constituents from a model

wastewater treatment train. The treatment process includes the following technologies in sequence:

- Pretreatment
- Primary clarifier
- Trickling filter
- Equalization
- Aeration 1
- Aeration 2
- Secondary clarifier

6.2.3 WATER7 Analysis Methodology

To model raw wastewater load disposition, the following analysis methodology was used:

- Default values were determined for many of the treatment modules. These values were then used in conjunction with facility-specific information to run the model.
- Facilities that provided survey information were considered for modeling.
- Facilities were grouped based on subcategory type as either a Subcategory A/C facility or a Subcategory B/D facility. Facilities with Subcategory A and/or C manufacturing processes that also included some Subcategory B and/or D manufacturing processes were grouped as Subcategory A/C facilities.
- Facilities were grouped based on their discharge status as either direct or indirect dischargers.
- For each subcategory and discharge group, an assessment of which facilities to model was conducted based on the following criteria:
  - If a facility did not have raw wastewater loadings of constituents that are candidates for regulation, the facility was not modeled.

— If a facility did not have any in-plant or end-of-pipe treatment that could be modeled by the WATER7 treatment modules, the facility was not modeled.

— For Subcategory A/C indirect discharge facilities, end-of-pipe treatment train categories were developed and a subset of the facilities in each category was modeled.

— When a treatment train could not be modeled, an engineering judgment was made concerning the accuracy of the organic load disposition reported by the facility in the survey.

Several of these methodology steps are discussed further below.

6.2.3.1 Sources of Data

All pollutant loading data used in the analysis came from Table 3-2 of the Section 308 Survey; if only part of the total flow or loading went through certain treatment units, data from Table 4-8 of the Section 308 Survey were used. Wastewater treatment system data were obtained from Table 5-2 of the Section 308 Survey and the facility diagram. Data on the flow rate through the treatment units were found on the facility diagram and in Table 7-1 of the Section 308 Survey.

6.2.3.2 Facility Groupings

As mentioned above, the 244 pharmaceutical manufacturing facilities that responded to the survey were grouped according to manufacturing processes and discharge type. After removing 7 zero-discharge facilities, the remaining 237 facilities were divided into four groups: (1) A/C directs, (2) B/D Directs, (3) A/C Indirects, and (4) B/D Indirects. Pollutant loadings from Table 3-2 of the Section 308 Survey were examined to determine which facilities reported raw wastewater loadings of pollutants that are candidates for regulation. Facilities with treatment systems and loadings of the pollutants of interest were considered for modeling. Table 6-2 presents the number of facilities considered for modeling.

TABLE 6-2

NUMBER OF FACILITIES CONSIDERED FOR MODELING

Facility Group	Total Number of Facilities	Number of Facilities With No Wastewater Treatment or Without Pollutant Loading Data	Number of Facilities With Pollutants of Interest	Number of Facilities Modeled
A/C Direct Dischargers	24	7	17	17
B/D Direct Dischargers	14	5	9	6
A/C Indirect Dischargers	88	30	58	12
B/D Indirect Dischargers	111	91	20	18
Zero Discharge	7	N/A	N/A	0

Source: Section 308 Survey data and Radian Corp. estimates.

Most of the Subcategory A/C and B/D direct discharge and Subcategory B/D indirect discharge facilities were modeled individually. The largest group available for modeling, the Subcategory A/C indirect discharge facilities, was subdivided into groups based on similarities in treatment trains. The subgroups included facilities with:

- Neutralization only
- Primary treatment only
- Secondary treatment only
- Both primary and secondary treatment
- Other treatment

The last subgroup listed is discussed below. The other subgroups were further divided based on initial modeling results. Facilities with enclosed neutralization only were separated from those with open neutralization units. Within both the primary only and the primary and secondary groups, facilities with equalization without mixing and enclosed equalization with mixing were grouped separately from those facilities with open equalization with mixing.

6.2.3.3 Treatment Units That Could Not Be Modeled

For facilities that showed no onsite treatment or primary treatment only, EPA reviewed the facility's reported organic load disposition for reasonableness. Based on these reviews, EPA either concurred with the load disposition reported by the facility or found that the load identified as degraded/destroyed could not be justified and made adjustments to the disposition loads accordingly.

In some cases, the information provided in the survey was unclear or included a treatment unit for which no WATER7 module has been developed (e.g., incineration or stripping) early in the treatment train. For those facilities, the survey responses were evaluated for reasonableness and either accepted as reported or adjusted based on engineering judgment according to the data provided. If a treatment unit not included in the modeling, such as a

trickling filter, was found near the end of a treatment train, the treatment train was modeled up to that point and the remaining pollutant loading, if any, was assumed to be present in the wastewater discharge.

SECTION SEVEN

ASSESSMENT OF BENEFITS

7.1 INTRODUCTION

This section presents an assessment of the benefits from the proposed effluent guidelines for the pharmaceutical industry. This assessment considers the human health, environmental, and economic benefits from reductions in effluent loadings and air emissions expected to result from the proposed rule considering the selected regulatory options. The assessment includes a qualitative description of each benefit category. In addition, it provides quantitative estimates of economic benefits for those benefit categories for which there are sufficient data to develop such estimates.

7.1.1 Overview of Benefits Assessment

A broad range of benefits might result from environmental controls, including improvement in or maintenance of human health, environmental quality, and economic welfare. Table 7-1 provides one example framework for categorizing the benefits of actions to reduce environmental pollution, including consideration of the benefits resulting from direct and indirect use of environmental resources.

In general, assessing the benefits of environmental regulation includes three steps: (1) evaluating the physical effects of the regulation, such as the changes in contaminant concentration levels in effluent discharges; (2) identifying the categories of benefits expected to result from these physical changes; and (3) evaluating the scope and magnitude of these benefits, both qualitatively and quantitatively. Identifying and evaluating economic benefits involves translating physical effects into changes in the provision of goods and services valued by society. For example, reduced toxic loadings in effluent discharges might lead to human health benefits. These benefits might stem from reductions in cancer risk and/or reductions in the systemic

TABLE 7-1

EXAMPLE FRAMEWORK OF BENEFIT CATEGORIES

Categories of Benefits	Types of Benefits
Human Health	■ Avoided Mortality Effects — cancer — noncancer ■ Avoided Morbidity Effects — acute effects — chronic effects
Environmental Resources	■ Direct Use Values — recreational opportunities ■ Ecological Services — provision of habitat ■ Passive Use Values
Economic Welfare	■ Production — agriculture — commercial fishing — timber supply ■ Avoided Materials Damage ■ Maintenance and Enhancement of Water Supply (quality and quantity) ■ Maintenance and Enhancement of Aesthetics — visibility — odor

effects associated with these toxics. In addition, reductions in toxic loadings in effluent discharges can generate environmental benefits by improving water quality, thus improving recreational opportunities for the public.

Benefits assessment of a proposed rule requires consideration of the likely incremental effect of the rule on human health and environmental quality. For example, a change in emission levels should be measured as the difference between the level of emissions with the rule and the baseline level of emissions in the absence of the rule. The benefits assessment presented below uses such an incremental approach.

The next part of this section identifies the benefit categories considered in this assessment. The remainder of the section describes the approach used to generate benefit estimates for each of these categories.

7.1.2 Benefit Categories Addressed in This Benefits Assessment

Section Six provides estimates of reductions in effluent loadings from pharmaceutical facilities expected to result from the proposed regulation and the resulting reductions in emissions of VOCs. A variety of human health, environmental, and economic benefits might result from these reductions. In particular, this assessment addresses the following benefit categories:

- Human health benefits due to reductions in excess cancer risk;
- Human health and agricultural benefits due to reductions in emissions of ozone precursors (i.e., reductions in VOC emissions);
- Ecological and recreational benefits due to improved water quality;
- Benefits from reductions in interference and pass through problems and improvements in worker health and safety at publicly owned treatment works (POTWs); and

- Human health benefits due to reductions in systemic and other risks, such as risk of respiratory, digestive, circulatory, neural and developmental effects, or individual organ toxicity.

For the first two benefit categories, sufficient information is available to monetize the benefits of the proposed rule. Sections 7.2 and 7.3 address these two benefit categories. Each section includes a qualitative description of these benefit categories, an overview of the approach used to monetize these benefits, a presentation of the resultant economic benefit estimates, and a review of the limitations of the valuation methods. The dollar magnitude of the benefits for the other three benefit categories could not be quantified. The next parts of this section (Sections 7.4 through 7.6) discuss these benefit categories qualitatively. Section 7.7 presents a summary of results.

7.2 REDUCTIONS IN CANCER RISK

This section describes the assessment of cancer risk reductions expected to result from this rule due to reductions in VOC emissions and reductions in pollutant loadings in wastewaters discharged to surface waters. Section 7.2.1 presents the results of the cancer risk assessment, estimating the number of excess cancer cases avoided due to the proposed rule, Section 7.2.2 describes the method used for valuing these effects, and Section 7.2.3 presents monetized estimates of the resulting human health benefits.

7.2.1 Description of Benefits

The analysis of the effects of the proposed rule, which were presented in Section Six, estimates the reduction in VOC emissions expected to result from the proposed rule. Many of these VOCs are carcinogenic and thus pose a risk to human health. Reductions in emissions of these substances therefore will result in reduced cancer risk in the exposed populations. In addition, the analysis estimates reductions in pollutant loadings to surface waters. These reductions will improve water quality and reduce cancer risk to the exposed populations from

ingestion of contaminated drinking water and fish tissue. The results from the cancer risk assessments for these exposure routes are described below.

7.2.1.1 VOC Emissions Reductions

Based on the cancer risk assessment for reductions in VOC emissions, it is estimated that the proposed effluent guidelines will result in the avoidance of 0.02 excess cancer cases per year nationwide (Versar, 1995). This estimated decrease in cancer risk results from reductions in emissions of 10 carcinogens, principally chloroform and methylene chloride. The number of excess cancer cases avoided is calculated as the difference in the estimated annual cancer incidence in the exposed population under baseline emission conditions and after implementation of the rule.

The Industrial Source Complex Long Term (ISCLT) air dispersion model in the Graphical Exposure Modeling System (GEMS) Atmospheric Modeling System (ISCLT/GAMS) is used to estimate the reduction in excess cancer risk likely to result from the proposed rule. Specifically, 33 facility/pollutant release combinations are modeled, using data provided by the pharmaceutical industry in response to EPA's Section 308 survey. The analysis considers cancer risk reductions at open air settling, neutralization, equalization, or treatment tanks at facilities directly discharging to surface waters.

Based on this analysis, it is estimated that 10 facility/pollutant release combinations currently exhibit cancer risk levels exceeding 10^{-6} for a portion of the exposed population. It is estimated that approximately 190 thousand people nationwide are exposed to carcinogens as a result of these releases (based on 1990 population data). The estimated reductions in emissions due to this rule are expected to result in 0.02 excess cancer cases avoided per year nationwide.

As discussed in Section Six, the emissions estimates reported in the Section 308 questionnaires might understate the quantity of VOCs released by the pharmaceutical industry and thus might understate the benefits of the proposed rule. To test the sensitivity of the resulting benefit estimates to this factor, an upper bound estimate of the level of VOC emissions

is developed based on a "maximum emissions" scenario. The maximum emissions scenario uses estimates of emissions reductions based on the WATER7 model.

Based on this scenario, the proposed rule will result in the avoidance of 0.35 excess cancer cases per year nationwide. This estimate also is developed using the ISCLT/GAMS model, considering 43 facility/pollutant combinations. Based on this analysis, 12 facility/pollutant combinations currently exhibit cancer risk levels exceeding 10^{-6}. It is estimated that 2.4 million individuals nationwide are exposed to carcinogens as a result of these pollutant releases.

7.2.1.2 Reductions in Pollutant Loadings to Surface Waters

Based on the cancer risk assessment, it is estimated that the proposed rule will result in about 0.002 excess cancer cases avoided per year due to reductions in risk from exposure to contaminants in fish tissue and drinking water. This estimate is small because the estimated cancer incidence from consumption of fish tissue and drinking water potentially affected by discharges from pharmaceutical facilities at current discharge levels is small.

The assessment of the cancer risk from consumption of contaminated drinking water and fish tissue evaluates the risks associated with the effluent from 17 direct dischargers for 44 pollutants and 116 indirect dischargers for 55 pollutants. The analysis first uses a stream dilution model to estimate instream pollutant concentrations based on current and projected discharge levels (Versar, 1995). The analysis then estimates lifetime average daily doses and individual risk levels for each pollutant discharged by a facility based on these instream pollutant concentration levels. The estimated individual cancer risk levels are aggregated on a facility basis and for those facilities with total risk exceeding 10^{-6}, cancer incidence in the exposed population is evaluated. In the case of cancer risk from pollutants in drinking water, the analysis considers exposure to the population served by drinking water utilities with intakes within 50 miles downstream of the discharge point. In the case of contaminated fish tissue, the analysis considers exposure to subsistence and recreational anglers and the general population.

For the fish tissue analysis, the estimated number of excess annual cancer cases avoided due to the proposed rule is less than 0.0001. At current discharge levels, total cancer risk to subsistence anglers exceeds 10^{-6} due to the discharge of eight carcinogens from four facilities into three streams. Given these risk levels and the size of the population exposed, however, estimated cancer incidence is small. Thus, while the proposed rule is expected to reduce the risk to acceptable levels (i.e., below 10^{-6}), the magnitude of the human health benefits is negligible. Total cancer risk for recreational anglers and the general population is not expected to exceed 10^{-6} for any discharges.

Similarly for the drinking water analysis, the estimated number of excess cancer cases avoided per year due to the proposed rule is small, at 0.002 cases. Based on this analysis, three streams receive discharges from ten facilities of seven carcinogens at risk levels exceeding 10^{-6}. However, only two of the streams have drinking water utilities within 50 miles downstream of the discharge point. Cancer incidence for these two streams is analyzed both under current discharge levels and projected levels under the proposed rule, yielding an estimate of the number of excess cancer cases avoided of 0.002.

7.2.2 Valuation Methodology

To value the reductions in cancer risk expected to result from this rule, an estimate of the range of the value of avoided mortality (also known as the value of a statistical life) is applied to the number of excess cancer cases avoided. The estimated range of the value of life used in this analysis is $0.6 million to $13.5 million, with a best estimate of $4.8 million (1990 $).[1] This range is based on a review of the value of life literature conducted for EPA's Office of Air and Radiation (OAR).[2] OAR undertook that analysis to support its retrospective assessment of the

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[1]This best estimate is the average of 26 value-of-life estimates identified as most appropriate for policy analysis purposes, as discussed later in this chapter.

[2]See Unsworth et al. (1992) and Neumann and Unsworth (1993). Note that this estimate also has been used in assessing the economic benefit of proposed environmental tobacco smoke legislation (U.S. EPA, 1994a).

costs and benefits of the Clean Air Act as mandated under Section 812 of the 1990 Clean Air Act Amendments.

OAR's review of the value of life literature considered estimates of the value of life from 39 wage-risk, contingent valuation, and consumer market behavior studies. Wage-risk studies estimate the value of life considering individuals' implicit trade-off between job-related mortality risk and compensation. Contingent valuation studies provide estimates of the value of life based on individuals' expressed willingness to pay to avoid hypothetical increments of mortality risk. Consumer market behavior studies consider risk-dollar tradeoffs made by individuals based on observed purchasing behavior in consumer markets (e.g., dollars spent in purchasing car options that improve automobile safety).

The 39 studies considered in OAR's review of the literature were identified earlier in literature reviews by Viscusi (1992, 1993) and Fisher et al. (1989). These studies were screened to identify estimates considered reasonable and reliable for policy analysis purposes. OAR selected 26 estimates from 23 studies based on four criteria suggested by Viscusi (1992) for considering the applicability of value of life estimates to policy analysis. These four criteria are:

- **Use of appropriate risk measures**—Some wage-risk studies rely on actuarial data to determine risk levels faced by workers in making a wage-risk tradeoff. This approach will bias the estimated value of a statistical life downwards because actuarial data are not limited to work-related risks; they include all types of risk faced by an individual.

- **Adequate sample size**—Some contingent valuation studies are based on small sample sizes, reducing the reliability of the resulting estimates.

- **Model type**—The results of labor market studies that focus on the value of a life-year or the implicit discount rate people apply to the value of a life-year yield less robust estimates of the value of life, due to the complexity of the structural models used in developing these estimates.

- **Use of appropriate willingness to pay proxies**—Viscusi (1992) finds that the consumer market studies he reviewed failed to provide an unbiased estimate of the value of life. The resulting estimates are biased because these studies had to assume values either for the level of risk or dollars spent to reduce this risk to estimate the value of life from the observed risk-dollar tradeoffs. These assumptions reduce the reliability of the resulting value of life estimates.

The resulting range of $0.6 million to $13.5 million reflects the entire range of the 26 selected value-of-life estimates.

This estimate of the range of the value of life is similar to other reported estimates of the range of the value of life. For example, based on his expert judgement, Viscusi finds that most of the reasonable estimates of the value of life are clustered in the $3.0 to $7.0 million range. In addition, the range applied in this analysis encompasses the range applied in EPA's recent RIA of the effluent guidelines for the pulp and paper industry (U.S. EPA, 1993). In that assessment, EPA applied a range of the value of life of $2.0 million to $10.0 million in 1992 dollars (equal to $2.0 million to $9.6 million in 1990 dollars). That range was based on a review of the literature conducted by Fisher et al. (1989). A $0.6 million to $13.5 million range is applied because this range includes estimates of the value of life from recent studies, including several published since the Fisher et al. study was completed.

7.2.3 Valuation of Benefits

Applying this estimated range of the value of life to the estimate of excess cancer cases avoided based on the Section 308 data (0.02 cases avoided), the human health benefits from reductions in cancer risk associated with this rule are valued at $12 thousand to $270, thousand (1990 $). These benefit estimates represent annual nationwide benefits for the proposed rule resulting from cancer risk reductions due to exposure both through inhalation and ingestion of carcinogens. This analysis is summarized in Table 7-2.

An upper bound estimate of the cancer risk reduction benefits is generated based on the maximum emissions scenario. Applying the value of life range to the upper bound estimate of the number of cancer cases avoided (0.35 cases avoided) yields benefits on the order of $210 thousand to $4.7 million per year. This analysis also is summarized in Table 7-2.

TABLE 7-2

ESTIMATED ANNUAL HUMAN HEALTH BENEFITS FROM CANCER RISK REDUCTIONS (1990 dollars)

	Section 308 Data			Maximum Emissions Data		
	Low	Best Estimate	High	Low	Best Estimate	High
Number of Excess Cancer Cases Avoided	0.02	0.02	0.02	0.35	0.35	0.35
Value of Life (million)	$0.6	$4.8	$13.5	$0.6	$4.8	$13.5
Total Benefits	$12,000	$96,000	$270,000	$210,000	$1,680,000	$4,725,000

7.2.4 Limitations

Apart from the uncertainty in the emissions data, there are several limitations to the risk assessment methodology and valuation approach used in this benefits assessment that might contribute to uncertainty in the resultant human health benefit estimates. These limitations are discussed below.

7.2.4.1 Risk Assessment Methodology Limitations

Limitations in the cancer risk assessment methods applied in this analysis introduce uncertainty to the resulting benefits estimates. These limitations largely result from the assumptions used in estimating exposure levels and the size of the population exposed. This section lists some of the assumptions used in the analysis. A more complete discussion of the assumptions used and their effects on the resulting benefit estimates appears in Versar (1995).

The cancer risk assessment incorporates many assumptions in evaluating exposure levels from inhalation of carcinogens and consumption of contaminated fish tissue and drinking water. For example, in modeling fugitive air emissions from pharmaceutical facilities and the resulting exposure levels, the ISCLT/GAMS model uses a gaussian air dispersion algorithm, and relies on assumptions related to facility characteristics (e.g., height of the stack), wind speed and direction, and weather conditions (based on averages). In addition, the dilution model used in estimating instream concentration levels assumes that complete mixing of discharge flow and stream flow occurs. This mixing assumption implicitly results in the calculation of an average stream concentration, although the actual concentration might vary across the width and depth of the stream. Further, pollutant fate processes such as sediment adsorption, volatilization, and hydrolysis are not considered in the model; this simplification might overstate the instream concentrations of pollutants.

The risk assessment also applies many assumptions in determining the exposed population and estimating the likely cancer incidence. For example the following assumptions are made in

estimating risks to subsistence and recreational anglers and the general population from consumption of contaminated fish tissue and drinking water:

- Populations potentially exposed to discharges are estimated based on the population of the state in which the facility is located;
- The potentially exposed population within in each state is estimated based on the ratio of the affected river miles (estuary square miles) to total river miles (estuary square miles) within the state;
- Commercially or recreationally valuable species are assumed to inhabit the waters in the vicinity of the discharges;
- Five percent of the resident anglers in a state are assumed to be subsistence anglers and the remaining 95 percent are assumed to be recreational anglers; and
- Cancer incidence in part is estimated assuming that subsistence and recreational anglers share their catch with other members of their households.

Finally, the assessment makes many assumptions commonly employed by EPA in evaluating cancer risks, including use of high dose-response information to predict low dose-response toxicity in deriving cancer slope factors, extrapolation from cancer effects observed in animal studies to effects in humans, and use of the 95 percent confidence limit of response. These assumptions are considered conservative, and thus might overestimate risk levels.

This discussion of some of the assumptions used in the cancer risk assessment is not meant to be comprehensive; rather it is meant to show that there is a significant level of uncertainty associated with the benefits estimates from the analysis. Some assumptions might result in overstatement of risk levels, while others might result in understatement of risk levels. The overall level and direction of bias and uncertainty introduced by these assumptions is unclear.

7.2.4.2 Valuation Methodology Limitations

There is significant uncertainty associated with the valuation method used to monetize these human health benefits. The underlying studies used to construct the range of the value of life applied in this analysis primarily consider the risk-dollar tradeoffs observed in the labor market. However, there are obvious differences in the nature of cancer mortality risk and job-related acute fatality risk. For example, premature mortality risks from exposure to pollution are experienced on an involuntary basis and generally are uncompensated, while job-related risks are assumed by individuals who presumably have some choice of occupation and are compensated for taking a riskier job. In addition, job-related risks tend to be more immediate, whereas cancer effects tend to be incurred later in life, but involve some pain and suffering. Differences in the nature of the mortality risk might imply differences in the value of these risks.

In addition, there are several issues related to transferring value-of-life estimates from the existing literature to value benefits associated with cancer risk reductions resulting from the proposed rule. These benefits transfer issues might bias the resulting benefits estimates, although the direction of the bias is unclear. These issues include:

- **Potential differences in the duration of life lost (i.e., the age of the affected individual).** Existing studies indicate that the age of an individual influences the value of life. Therefore, if the age distribution of the individuals affected by this proposed rule does not match the age distribution of the individuals considered in the studies from which the value-of-life estimates were developed, transferring these value-of-life estimates to this analysis might bias the resulting benefit estimates.

- **Potential differences in the level of baseline risk.** Individuals are likely to value reductions in risk differently depending on their level of baseline risk. Thus, if the level of baseline risk faced by individuals affected by the proposed rule differs from the risk level faced by individuals considered in the existing value-of-life studies, transferring these value-of-life estimates to this analysis might bias the resulting benefit estimates.

- **Potential differences in income levels.** Based on economic theory, and as estimated by Viscusi and Evans (1990), the value of life increases with increasing income. Thus, if the average income of individuals affected by the cancer risk addressed by this rule differs from the income of individuals considered in the value-of-life literature, transferring these value-of-life estimates to this analysis might bias the resulting benefit estimates.

In this assessment, no adjustments are made to the estimated range of the value of life to account for possible differences in the nature of risk or for these other sources of potential bias. However, because the cancer risk reduction benefits are evaluated using a range, the resulting human health benefit estimates might reflect the uncertainty resulting from these limitations.

7.3 REDUCTIONS IN EMISSIONS OF OZONE PRECURSORS

The proposed effluent guidelines are expected to result in a reduction in VOC emissions.[3] Controlling VOC emissions is beneficial because VOCs are precursors to ozone, which negatively affects human health and the environment. For example, ozone has been found to reduce lung function in humans and to reduce agricultural crop yields. Ozone formation also might affect tree growth, cause materials damage, and affect visibility (Krupnick and Kopp, 1988).

This assessment of the benefits from reductions in emissions of ozone precursors considers two potential categories of benefits:

- Human health benefits associated with reductions in acute health effects; and
- Economic welfare benefits due to increased agricultural yield.

This assessment does not address human health benefits from reductions in chronic health effects nor does it address economic welfare benefits related to forest growth, materials damage, or visibility. The benefits associated with these categories could be significant, and thus the benefit estimates presented below might understate the total benefits of the proposed rule.

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[3]This analysis excludes two organic pollutants, methylene chloride and trichlorofluoromethane, from the estimated reductions in emissions of ozone precursors. These two organic pollutants were identified for exclusion based on a final rule recently promulgated by EPA that defines VOCs for the purposes of developing state implementation plans to attain national ambient air quality standards (NAAQS) for ozone (U.S. EPA 1994b). This definition excludes specified compounds that have negligible photochemical reactivity and thus do not contribute significantly to the formation of tropospheric ozone, including methylene chloride and trichlorofluoromethane.

Reactions between VOCs and nitrogen oxides (NO_x) form ozone in the presence of sunlight. However, ozone formation is a complicated process that is not well understood. This uncertainty prevents estimation of the specific changes in ozone concentrations that are likely to occur due to the reductions in VOC emissions expected to result from the proposed rule. In this analysis, the benefits from VOC emissions reductions are evaluated assuming a linear relationship between VOC emissions and economic benefits from reductions in ozone concentrations, as described below.

Both the human health and economic welfare benefits of reduced emissions of ozone precursors are evaluated applying a benefits transfer approach. In both cases, estimates of the average value per megagram (Mg) reduction in VOC emissions are applied to the estimated total reduction in VOC emissions in nonattainment areas due to this rule. The value per Mg estimates used in this assessment are based on the results of a study by the U.S. Congress, Office of Technology Assessment (OTA, 1989).

The next sections present the results of the assessment of the human health and economic welfare benefits associated with reductions in emissions of VOCs. First, more detailed qualitative descriptions of each benefit category are presented. Second, the methodology used to monetize these benefits is discussed. Third, the results of the analysis are summarized. Finally, the limitations associated with the valuation approach are described.

7.3.1 Human Health Benefits

7.3.1.1 Description of Benefits

Clinical and epidemiological studies have demonstrated that short-term exposure to elevated ozone concentration results in acute effects on human health. These acute effects include respiratory and nonrespiratory symptoms, such as shortness of breath, headaches, and pain upon deep inhalation; minor restricted activity days; and asthma attacks. Reductions in ambient ozone concentrations reduce the incidence of these acute human health effects, thus generating economic benefits.

In addition, ozone is believed to have chronic effects on human health. For example, laboratory studies have observed chronic effects on animals exposed to elevated levels of ozone, including increased susceptibility to infection, decreased pulmonary function, and some fibrotic-like lung damage, which could lead to respiratory diseases such as chronic bronchitis (Krupnick and Kopp, 1988). The link between ozone concentration and chronic health effects in humans, however, is not well understood. Therefore, this category of human health benefit is not considered quantitatively in this analysis.

This analysis considers human health benefits resulting from reductions in VOC emissions in nonattainment areas. Nonattainment areas include counties that do not meet EPA's current ozone standard. This approach is consistent with the approach used in the OTA study, which considers human health benefits in metropolitan statistical areas with ozone concentrations exceeding EPA's ozone standard. Consistency with that approach is important because the values used to monetize these human health benefits are based on the OTA study, as discussed below. However, reductions in ozone levels in attainment areas also might lead to human health benefits. Some individuals might experience health effects due to exposure to ozone concentrations at concentrations below the current ozone standard. These individuals would benefit from the expected reductions in VOC emissions in attainment areas. This analysis excludes these benefits and therefore will understate the benefits of this rule.

7.3.1.2 Valuation Methodology

To monetize the human health benefits associated with reductions in VOC emissions, a benefits-transfer-based approach is used. Specifically, the estimated reductions in VOC emissions in nonattainment areas are multiplied by an existing estimate of the value per Mg reduction in VOC emissions. The VOC emission reductions expected to occur in nonattainment areas due to the proposed rule are estimated based on the emissions reductions data described in Section Six, combined with information on whether the affected facilities are located in nonattainment areas.

The value per Mg reduction in VOC emissions is based on the results of the OTA study (1989). That study evaluated the annual nationwide human health benefits of controlling VOC emissions to reduce ozone levels in nonattainment areas. One scenario in the OTA study considered the human health benefits expected to result from a 35 percent reduction in 1985 VOC emission levels in nonattainment areas. Based on the results of this scenario, the benefits associated with reduced VOC emissions would be expected to fall in the range of $19 and $1,209 per Mg (1990 $). This range represents the average value per Mg reduction in emissions, assuming a 3.5 million Mg reduction in VOC emissions and total human health benefits ranging from $67 million to $4,233 million per year (1990 $), with an average value of $2,150 million. The resulting unit values are summarized in Table 7-3.

7.3.1.3 Valuation of Benefits

Applying the method described above, the estimated annual human health benefits resulting from reductions in VOC emissions ranges from $27 thousand to $1.7 million, depending on the unit value used. Based on the Section 308 data, it is estimated that the proposed regulations will reduce VOC emissions in nonattainment areas by 1,396 Mg per year (U.S. EPA, 1995c). This reduction represents 10.1 percent of the estimated total reduction in VOC emissions in all areas (i.e., both attainment and nonattainment). Applying the unit-value estimates to this quantity yields estimates of the monetary value of the resulting human health benefits ranging between $27 thousand and $1.7 million per year, with an average of $857 thousand. These results are summarized in Table 7-4.

7.3.1.4 Limitations

Several limitations to the valuation approach applied above contribute to uncertainty in the resultant human health benefit estimates. First, the estimates might understate the human health benefits because they do not include potential benefits from avoided chronic human health effects. Second, the application of a range of values per Mg reduction in VOC emissions might overstate or understate the benefits of the proposed rule because the value range used

TABLE 7-3

DERIVATION OF HUMAN HEALTH BENEFITS PER MEGAGRAM REDUCTION IN VOC EMISSIONS IN NONATTAINMENT AREAS

	Low	Average	High
Total Annual Benefits Assuming a 35 Percent Reduction in VOC Emissions (millions of 1990 $)*	$67	$2,150	$4,233
Total Expected Reduction in VOC Emissions (millions of Mg)*	3.5	3.5	3.5
Benefits per Mg Reduction in VOC Emissions (1990 $/Mg)	$19	$614	$1,209

*Based on OTA (1989). Values from the OTA study are converted from 1984 to 1990 dollars using the GDP implicit price deflator.

Source: IEc estimate.

TABLE 7-4

ESTIMATED ANNUAL HUMAN HEALTH BENEFITS FROM REDUCTIONS IN VOC EMISSIONS IN NONATTAINMENT AREAS
(1990 dollars)

	Section 308 Data		
	Low	**Average**	**High**
Value per Mg	$19	$614	$1,209
VOC Emissions Reductions in Nonattainment Areas (Mg)	1,396	1,396	1,396
Total Benefits	$27,000	$857,000	$1,688,000

Source: IEc estimates.

reflects the average value for a 35 percent reduction in VOC emissions rather than the marginal value of the incremental reductions resulting from this rule. If the marginal benefits from incremental reductions in VOC emissions are assumed to be higher (lower), application of this range of values would understate (overstate) the benefits of the rule. In addition, the benefits estimates from the OTA study (used in estimating the value per Mg reduction in VOC emissions) are based on 1984 data on population in metropolitan areas. Thus the benefits estimates might understate the benefits of the proposed rule because they do not take into account population growth between 1984 and 1990.

Third, uncertainty associated with the relationship between VOC emission levels and ozone formation contributes to uncertainty in the resultant benefit estimates. For example, recent research suggests that the relative atmospheric concentrations of VOCs and NO_x affect ozone formation (National Research Council, 1991). Thus, the relationship between VOC emissions reductions and changes in ozone concentrations might not be linear, as assumed in this analysis. The direction of bias introduced by this factor is unknown.

Finally, the analysis assumes that there are no benefits associated with reduced VOC emissions in areas in attainment with the ozone standard. If there are human health benefits associated with such reductions, the analysis will understate the total benefits of this rule. The magnitude of these benefits could be significant, potentially doubling the estimated benefits of the rule.[4]

7.3.2 Welfare Benefits from Increased Agricultural Crop Yields

7.3.2.1 Description of Benefits

Studies of the relationship between ambient ozone concentrations and greenhouse-controlled ozone concentrations and agricultural crop yield demonstrate that ozone negatively

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[4]Assuming that there are benefits from such reductions and applying the average value per Mg reduction of $614 to the expected VOC emissions reductions in attainment areas yields a benefit estimate ranging from $7.0 million to $7.6 million for this benefit category.

affects crop yield. These studies show that exposure to ozone reduces plant growth due to reduced photosynthesis and transport of carbohydrates in plants. Reductions in crop yield can in turn affect agricultural production, crop prices, and incomes of agricultural producers, and thus can affect social welfare.

In addition, biological research has established that air pollution can affect not only the yield, but also the quality of agricultural crops (Shortle et al., 1988). A reduction in quality might correlate with a reduction in the nutritional value of the crop. In this case, the food value of the crop would be reduced even if the yield remained constant. If qualitative attributes are a determinant of the demand for a commodity, changes in demand will result in changes in price, production, and economic welfare.

Ozone-induced crop yield changes might have secondary effects due to the responses of the agricultural community to the yield change. It is a common agricultural practice to counter decreased crop yields with increased use of fertilizer. In addition, crops suffering from the effects of ozone are more susceptible to pestilence, prompting farmers to increase their use of pesticides. Increased fertilizer and pesticide use represents an economic cost to agricultural producers, thus reducing total economic surplus. Furthermore, a reduction in crop yield often leads to an increase in the acreage of cultivated land to compensate for yield loss. Ozone-induced decisions to increase the amount of cultivated land could lead to the loss of wildlife habitat, increased soil erosion, and increased agriculture-related pollution. Increased soil erosion, fertilizer use, and pesticide use will further increase agriculture's contribution to surface and ground-water pollution.

Although the economic implications of these secondary effects of reduced crop yields might be significant, this analysis only considers crop productivity impacts. Existing estimates of the secondary environmental impacts of reduced crop productivity have not been identified and thus these benefits have not been quantified. Therefore, the resulting benefit estimates will understate the agricultural-related economic benefits of the proposed rule.

7.3.2.2 Valuation Methodology

The economic welfare benefits expected to result from reductions in VOC emissions and the resulting change in crop yields are evaluated applying a benefits-transfer-based approach. Specifically, the estimated reductions in VOC emissions in nonattainment areas are multiplied by an existing estimate of the value per Mg reduction in VOC emissions (based on the OTA study). These VOC emission reduction estimates are the same as those used in the evaluation of human health benefits in the previous section.

OTA estimates the range of economic benefits expected to result from changes in crop yields based on two studies: Krupnick and Kopp (1988) and Adams and Glyer (1988). These two studies use economic models to estimate the net change in social welfare resulting from higher crop yields that occur as a result of lower ambient ozone levels in rural areas. These models consider the changes in production, prices, and producer costs to evaluate the change in producer and consumer surplus.[5]

The estimated values from these two studies range between $117 and $198 per Mg reduction in VOC emissions (1990 $). This range reflects differences in the models used in the two studies. These models apply differing assumptions regarding the relationship between ozone levels and crop yields, differing economic parameters (e.g., different crop prices), and differing ozone concentration data, and consider differing crops. The crops considered in these models include corn, wheat, soybean, cotton, barley, alfalfa, sorghum, oats, peanuts, grass-legume hay, and rice. Table 7-5 shows the derivation of the benefit estimates for reductions in ambient ozone levels based on these two studies.

This benefits assessment evaluates agricultural benefits in nonattainment areas only due to uncertainty in the effect of reductions in VOC emissions in rural areas on ozone

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[5]Producer surplus represents the difference between what a producer receives for a good and the minimum amount that the producer would accept rather than forego sale of the good. Consumer surplus represents the difference between the maximum amount a consumer would pay rather than forego consuming the good and the amount the consumer actually pays for the good.

TABLE 7-5

DERIVATION OF ESTIMATED AGRICULTURAL BENEFIT PER MEGAGRAM REDUCTION IN VOC EMISSIONS

	Low*	Average	High*
Total Benefits from a 10 Percent Reduction in Ozone Concentrations** (millions of 1990 $)	$269	$363	$456
Total Reduction in VOC Emissions (millions of Mg)	2.3	2.3	2.3
Benefit per MG Reduction in VOC Emissions (1990 $/Mg)	$117	$158	$198

*The low value is based on the results of Krupnick and Kopp (1988) while the high value is based on the results of Adams and Glyer (1988), as reported in OTA (1989). Values were converted from 1986 to 1990 dollars using the GDP implicit price deflator.

**These economic models evaluated the benefits expected to result from a reduction in ozone concentrations by 10 percent of the difference between then-current ambient ozone concentrations and background ozone levels.

Source: IEc estimates.

concentrations in these areas. Recent research has considered the effectiveness of NO_x versus VOC control in reducing ozone levels. These studies suggest that the effectiveness of VOC controls in reducing ozone formation depends on the ambient levels of VOCs and NO_x. In general, VOC control will be less effective in areas with a high VOCs to NO_x ratio than in areas with a low ratio. For example, the OTA study states that "[r]ecent modeling studies that have simulated typical rural conditions suggest that outside of urban and industrial plumes, reducing NO_x emissions will generally be a more effective strategy for lowering ozone than reducing VOC emissions." (OTA 1989). This research suggests that reductions in VOC emissions in rural areas may not have as large of an effect on ozone levels in rural areas as might be hoped. Unfortunately it does not provide insight into the relationship between reductions in VOC emissions and reductions in ozone levels in rural areas. To be conservative, the assessment only considers agricultural benefits from reductions in VOC emissions in nonattainment areas, assuming a linear relationship between VOC emissions reductions and reductions in ozone concentrations in these areas. Excluding potential agricultural benefits from reductions in VOC emissions in attainment areas is likely to result in understating the benefits of the proposed rule.

7.3.2.3 Valuation of Benefits

Applying the valuation method outlined above, the estimate of the agricultural benefits from reductions in VOC emissions ranges from $163 thousand to $276 thousand per year (1990 $). A summary of these economic benefit estimates is presented in Table 7-6.

7.3.2.4 Limitations

There are several limitations to the valuation approach used in estimating the agricultural benefits resulting from reductions in VOC emissions. One of the principal limitations involves the benefits-transfer-based approach applied in developing the benefit estimates. This approach might overstate expected agricultural benefits because of differences in the magnitude of the physical effects estimated for the proposed rule and the magnitude of the effects considered by

TABLE 7-6

ESTIMATED ANNUAL ECONOMIC WELFARE BENEFITS FROM REDUCTIONS IN OZONE-INDUCED IMPACTS ON AGRICULTURE (1990 dollars)

	Section 308 Data		
	Low	**Average**	**High**
Value per Mg	$117	$158	$198
Reductions in VOC Emissions (Mg)	$1,396	$1,396	$1,396
Total Benefits	$163,000	$221,000	$276,000

Source: IEc estimates.

OTA (1989). The magnitude of the change in ozone concentration evaluated by OTA is orders of magnitude larger than that of the likely reductions due to this proposed rule.

A second limitation to this approach is that the resulting estimates might understate the agricultural benefits because they do not include potential benefits from reductions in VOC emissions in attainment areas. Studies have shown that ozone concentrations in excess of background levels affect crop yields (OTA 1989, Krupnick and Kopp 1988); this finding suggests that reductions in ozone concentrations in attainment areas might generate agricultural benefits. Although reductions in VOC emissions might not be as effective in reducing ozone in attainment areas as other approaches, such VOC emissions reductions could result in some reduction in ozone concentrations in these areas. The degree to which the resulting estimates understate the agricultural benefits is not known and depends on the relationship between VOC levels and ozone formation in rural areas.

A final limitation to this approach involves the assumption that for nonattainment areas, a linear relationship exists between reductions in VOC emissions and reductions in ozone levels. As discussed above, the relationship between VOC emissions and ozone formation is a complex process that is not well understood. It is not clear whether the assumed linear relationship will overstate or understate the agricultural benefits in nonattainment areas resulting from the proposed rule.

7.4 ENVIRONMENTAL BENEFITS

The proposed effluent guidelines are expected to generate environmental benefits by improving water quality. These improvements in water quality are expected to result from reduced loadings of toxic substances in the effluent of the regulated facilities and reduced interference and passthrough problems at POTWs. The environmental benefits expected to result from the proposed rule are discussed below. Related benefits from reduced interference and passthrough at POTWs are discussed in more detail in Section 7.5.

7.4.1 Description of Benefits

A wide range of environmental benefits is associated with the maintenance and improvement of water quality. These benefits include use values (e.g., recreational fishing), ecological values (e.g., provision of habitat), and passive use values.[6] For example, water pollution can affect the quality of the fish and wildlife habitat provided by water resources, thus affecting the species utilizing these resources. This effect in turn can affect the quality of recreational experiences of users, such as anglers fishing in the affected streams. In addition, individuals might value actions to preserve water resources even if they do not currently plan to use these resources. These passive-use values reflect the value placed on a resource for reasons other than direct human use, such as the value placed on knowing that the resource exists and on knowing that the resource will be available to future generations (Krutilla, 1967; Freeman, 1993).

The potential recreational benefits from improvements in water quality expected to result from the proposed rule are evaluated below. The analysis only develops an order-of-magnitude estimate of these benefits due to limitations in the available data. This analysis does not evaluate the ecological or passive-use-value benefits of the proposed rule because sufficient data to evaluate these benefits are not available. Ecological and passive-use values of water resources are potentially significant, however, and omitting these benefit categories from the benefit assessment will result in understating the environmental benefits of the proposed rule. Individuals have shown a general concern for and willingness to pay to maintain water quality and the habitat services provided by water resources, both through donations to conservation organizations and through responses to contingent valuation surveys. For example, public policies protecting natural resources and public and private expenditures on preserving the quality of water resources demonstrate that the public values these resources and is willing to pay and make financial sacrifices to preserve them. In addition, results from contingent valuation surveys considering willingness to pay for water quality improvements show that individuals hold significant positive values for water quality (e.g., see Desvousges et al., 1983; Fisher and Raucher, 1984; and Carson and Mitchell, 1988). Although these studies do provide an indication of

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[6]Human health benefits resulting from improvements in water quality, including cancer risk reductions and systemic risk reductions are evaluated in Sections 7.2 and 7.6.

individuals' concern for water resources and the order of magnitude of an individual's willingness to pay to preserve them, these studies do not meet current guidelines for conducting contingent valuation studies and thus do not provide data that can be used in estimating the ecological and passive-use benefits of the proposed rule.

7.4.2 Valuation Methodology

To estimate the economic value of the improvements in water quality expected to result from this rule, instream concentrations of toxic pollutants resulting from wastewater discharges by the affected facilities are modeled (Versar, 1995). Using a simple dilution model, these instream pollutant concentration levels are estimated for 17 facilities directly discharging 44 pollutants to 17 receiving streams and 116 facilities indirectly discharging 55 pollutants to 87 streams. These concentrations are modeled both under current conditions and under the proposed rule. The resulting instream concentration estimates are then compared to EPA's freshwater acute and chronic aquatic life criteria to evaluate whether these discharges pose risk to aquatic organisms.

The projected reductions in toxic loadings to surface waters is significant. For direct dischargers, pollutant loadings are estimated to decline by 98 percent, from 5.2 million pounds per year under current conditions to 0.1 million pounds per year under the proposed rule. Similarly, for indirect dischargers, pollutant loadings are estimated to decline 51 percent, from 34.8 million pounds per year under current conditions to 16.9 million pounds per year under the proposed rule.

The analysis comparing instream concentration levels to aquatic life water quality criteria estimates that current discharge loadings result in pollutant levels exceeding aquatic water quality criteria at two locations. The analysis also indicates that no pollutant levels exceeding water quality criteria are expected to occur at these two sites based on projected discharge loadings under the proposed rule. Thus the proposed rule is expected to result in a substantive change in water quality at these two sites. The two locations and pollutants of concern are Honey Creek, Indiana (ammonium hydroxide and isopropanol), and the Los Angeles River, California

(ethanol). Note that although improvements in water quality would be expected at other locations, these locations did not experience pollutant levels exceeding any water quality standard as a result of pharmaceutical industry discharges under current conditions.

The recreational benefits from the expected water quality improvements at these sites are estimated using a simple model. The model estimates the recreational benefits from water quality improvements based on the change in consumer welfare likely to result from improved angler catch rates at these sites. Although consumer surplus for a day of recreational fishing is a function of several site characteristics (including species mix, catch rate, fish size, and other site amenities), numerous studies have applied catch rate as a proxy for site quality, under the assumption that catch rate is an important determinant of the value that a recreational angler receives for a fishing day (e.g., Samples and Bishop, 1985; NAPAP, 1989). The model also assumes that these two sites are used by recreational anglers, that improvements in water quality at these sites will increase fish populations, and that recreational catch rates will increase with these increases in fish populations.[7]

7.4.3 Valuation of Benefits

Based on this assessment, it is estimated that the potential recreational benefits from the proposed rule are on the order of thousands of dollars per year. To develop this estimate, approximations of the number of trips per year at these sites, the change in fish population, and the change in consumer welfare due to increases in catch rate (i.e., the increased value per fishing trip) are used. Fishing pressure at these sites is estimated based on the estimated average number of fishing trips per river and stream mile per year in these two states and length of river or stream affected. The change in consumer welfare is estimated based on a value per trip ranging between $20 and $40 and an elasticity of consumer surplus equal to one (i.e., a one percent increase in catch is assumed to yield a one percent increase in consumer surplus).

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[7]Interviews with regional resource managers indicate that recreational fishing at the Los Angeles River site is unlikely, given a lack of access to the affected segment of this river and given the intermittent nature of the river.

7.4.4 Limitations

Limitations in the methods used in modeling instream concentration levels and in valuing the potential effects on recreational fishing introduce uncertainty to the benefits estimates. First, the approach used to model instream pollutant concentrations makes several assumptions, including:

- Background concentrations of each pollutant both in the receiving stream and the POTW influent are assumed to equal zero; thus only the ecological effects of discharges of the facilities addressed by the rule are evaluated.
- The analysis assumes complete mixing of discharge flow and stream flow. This mixing results in an estimated average stream concentration, whereas the actual concentration can vary across the width and depth of the receiving water.
- The pollutant load to the receiving stream is assumed to be continuous and representative of long-term facility operations.
- The analysis does not consider sediment adsorption, volatilization, and hydrolysis; this approach can result in concentration estimates that are higher than actual levels.

As a result of these assumptions, the model might overestimate or underestimate instream concentrations, thus affecting the extent to which the rule eliminates the occurrence of pollutant levels exceeding aquatic life water quality criteria. The overall effect of these assumptions is unclear.

Second, significant uncertainty is associated with the recreational benefit estimates due to the limited data available to assess these benefits. For example, there are no data on the expected effects of improved water quality on fish populations at these sites. In addition, the analyses incorporate assumptions on fishing pressure at the two sites, the length of the river affected by the discharges, the value of a fishing day, and the change in the value of a fishing day due to higher catch rates. For example, fishing pressure estimates for these two sites are based on state averages, since fishing pressure data for these sites are not available. Given the data

constraints, the benefits estimate for this benefit category is presented as an order of magnitude estimate.

7.5 EFFECTS AT POTWs

The proposed rule establishes pretreatment standards for 55 pollutants discharged to POTWs by pharmaceutical facilities. EPA identified the pollutants to be addressed by pretreatment standards based on analyses of the quantity of wastewaters discharged by facilities, pollutant concentration levels in these wastewaters, and the number of facilities that discharge these pollutants. This section qualitatively describes the potential benefits to POTWs resulting from these pretreatment standards.

7.5.1 Description of Benefits

This analysis considers three potential sources of benefits to POTWs from the proposed pretreatment standards:

- Reductions in the likelihood of interference, passthrough, and sewage sludge contamination problems;
- Reductions in health and safety risks to POTW workers; and
- Reductions in costs potentially incurred by POTWs in analyzing toxic pollutants and determining whether, and the appropriate level at which, to set local limits.

Each of these potential benefit categories is discussed below.

7.5.1.1 Reductions in Interference, Passthrough, and Sewage Sludge Contamination Problems

Toxic pollutants contained in the effluent loadings of pharmaceutical plants and discharged to POTWs can cause interference problems and/or pass through a POTW's treatment system and potentially affect water quality or contaminate sludges generated during treatment. Interference is defined as the inhibition or disruption of POTW operations. Interference can result from large quantities or high concentrations of toxic pollutants in effluent discharges that might adversely affect the operation of a POTW, potentially affecting the treatment efficiency or capacity of the plant. Similarly, passthrough can result when toxic pollutants in effluent discharges are not addressed by a POTW's treatment process or if the quantity or concentration of pollutants prevents the POTW from fully treating the wastewaters. These pollutants can remain in the wastewaters and be discharged by the POTW to surface waters. Alternatively, these pollutants can remain in the treatment sludges. Passthrough and sludge contamination problems affect POTWs to the extent that they prevent POTWs from meeting their permits or sewage sludge criteria.

Anecdotal evidence and analytic results indicate that such effects can occur. POTW responses to an EPA survey addressing toxic substances in effluent discharges by pharmaceutical manufacturers and the impact of these substances on POTW operations provides evidence that these effluent loadings can cause inhibition problems at POTWs (Radian, 1993). For example, one POTW indicated that high concentrations of volatile organics in a pharmaceutical facility's effluent might have caused nitrification problems at the POTW. Another POTW stated that low-level discharges of some compounds can affect treatment plant operations. For example, releases of siloxanes affected the efficiency of the POTW's boiler and ultimately forced the plant to replace this equipment.

As part of the analysis of the effects of pretreatment standards, POTW influent levels are compared to available data on inhibition levels (Versar, 1995). This analysis considers the potential impacts of effluent from 65 pharmaceutical facilities containing 51 pollutants discharged to 96 POTWs. Under current conditions, inhibition problems are projected to occur at six POTWs for seven pollutants. Inhibition problems are projected to occur at five POTWs for

three pollutants after the proposed rule. Sufficient data are not available to monetize this benefit category.

Limited evidence is available on the extent to which discharges from pharmaceutical facilities cause POTWs to fail to comply with their permits or result in pollutant levels in sewage sludges that exceed sewage sludge criteria. There are several documented incidents of large slug loads or accidental releases from pharmaceutical facilities that have negatively affected the environment, including fish kills, degradation of water quality, and odor problems (Versar, 1995).[8] In addition, currently many pollutants are not controlled in POTW permits because information is unavailable on the potential impacts of these pollutants on the environment. Although discharge and failure to treat unregulated pollutants technically does not constitute passthrough, these pollutants enter and potentially have negative effects on the environment. Finally, an analysis comparing sewage sludge concentration levels to sewage sludge quality criteria is not possible, since sewage sludge quality criteria for the 55 pollutants selected for regulation under the proposed rule have not been developed.

The proposed pretreatment standards might help reduce shock releases (i.e., unexpected releases that contain high concentrations of toxic pollutants) from pharmaceutical facilities and thus reduce the likelihood that these releases will cause interference, passthrough, and sewage sludge contamination problems at POTWs. The proposed pretreatment standards are expected to reduce toxic loadings in the industry's effluent, thus reducing the toxic loadings discharged to surface waters. The benefits from these effects, including health benefits and benefits from improved water quality, could be significant. However, sufficient data to quantify these benefits further are not available.

[8]Note that some of these releases might have been in violation of existing regulations, and thus it might be inappropriate to attribute benefits resulting from proper control of these releases to the proposed rule. However, if the proposed rule does reduce the likelihood of such releases, it might be argued that such benefits are attributable to the rule.

7.5.1.2 Benefits to POTW Worker Health and Safety

Toxic substances in effluent discharges to POTWs pose health risks to POTW workers. Volatilization of toxics from POTW influent could pose cancer risk to POTW workers or increase the risk of explosion at the plant. For example, in the survey of POTWs, one facility indicated that releases of sulfuric acid led to potential human health risk at the facility. The proposed rule is expected to reduce these risks, thus generating human health benefits.

Following procedures outlined in EPA's *Guidance to Protect POTW Workers from Toxic and Reactive Gases and Vapors* (U.S. EPA, 1992), risks to POTW workers from exposure to toxics are evaluated under current conditions and under proposed pretreatment standards (Versar, 1995).[9] Occupational exposure levels at POTWs are modeled based on the mixture of vapors that can partition out of influent water into the surrounding air. Risks to POTW workers are evaluated comparing these estimated exposure levels to occupational Threshold Limit Values (TLVs). For each POTW potentially affected by the proposed rule, hazard ratios (pollutant concentration/TLV) are estimated for each pollutant in the effluent of a facility discharging to the POTW; these ratios are aggregated to obtain an estimate of the overall hazard level. If the sum of the hazard ratios exceeds one, then POTW workers potentially are at risk.

Applying this approach, the proposed rule is estimated to reduce occupational risk at six POTWs. The analysis evaluates effluent discharged by 129 facilities to 85 POTWs. Based on current conditions, 12 POTWs treating 51 pollutants are estimated to have total hazard ratios greater than one. In contrast, six POTWs are estimated to have hazard ratios greater than one based on projected discharge levels under the proposed rule. Benzene is estimated to have the largest effects on POTW workers. Data are not available to monetize this benefit category.

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[9]The analysis does not consider risks to sewer workers, assuming that these workers would not be exposed to toxic emissions for long periods of time without using protective gear. The analysis considers risk levels assuming distillation pretreatment rather than steam stripping pretreatment as under the proposed rule, and thus provides an upper bound estimate of the reductions in risks to POTW workers under the proposed rule.

7.5.1.3 Benefits from Reductions in Analytical Costs

Under the National Pretreatment Program, authorized POTWs are required to develop and implement programs to control pollutants discharged by facilities to their systems. These local programs set numerical limits on toxic loadings in discharges to the POTW, based on national categorical pretreatment standards or local limits determined by the POTW. Local limits are designed to prevent passthrough, interference, and sewage sludge contamination, taking into account POTW-specific and effluent-specific characteristics, as well as to implement other specific components of the National Pretreatment Program (e.g., preventing discharges that might cause fire, explosion hazard, corrosive structural damage, or worker health and safety problems).

In setting these local limits, POTWs might need to undertake analyses to determine which pollutants warrant local limits and at what numerical level. Conducting these analyses is expensive—on the order of hundreds of thousands of dollars. Thus, establishing pretreatment standards benefits POTWs by allowing them to avoid the costs of performing these analyses. In addition, it is more efficient to conduct such analyses at the national level, reducing the potential for duplication of effort. Several POTWs contacted as part of the POTW survey indicated that they will benefit from the establishment of national pretreatment standards by avoiding these analytical costs. In addition, they indicated that the pretreatment standards will bolster the legal authority of the limits they set.

7.6 REDUCTIONS IN SYSTEMIC RISK

7.6.1 Description of Benefits

Exposure to toxic substances might pose risk of systemic and other effects to humans, including effects on the circulatory, respiratory or digestive systems and neurological and developmental effects. The proposed rule might generate human health benefits by reducing exposure to these substances, thus reducing the risks of these associated effects.

As in the case of the cancer risk assessment, systemic risks are evaluated for exposure from air emissions and consumption of contaminated fish tissue and drinking water. Modeled pollutant concentration levels are compared to human health criteria or estimated toxic effect levels. This analysis is performed using both the Section 308 data and the "maximum emissions" scenario data.

Based on the Section 308 data, the proposed rule is not expected to result in reductions in systemic risk due to reductions in air emissions because based on these data, baseline risk levels are low. (Versar, 1995). Under the maximum emissions scenario, the proposed rule is estimated to reduce systemic risk due to reductions in air emissions. The analysis estimates that 126,000 individuals will benefit from reductions in exposure to two toxic pollutants, triethylamine and 2-methoxyethanol. These two substances might have nasal and ocular effects or have testicular effects, respectively. For the drinking water and fish tissue exposure routes, under both data scenarios, the proposed rule is not expected to result in reductions in systemic risk because estimated concentration levels under current conditions are below human health criteria or toxic effect levels. Sufficient data to quantify these benefits further are not available.

7.7 SUMMARY OF RESULTS

The estimated annual benefits resulting from the proposed rule range from $202 thousand to $6.7 million (1990 $). This range reflects uncertainties in estimating the physical effects of the proposed rule and in placing a dollar value on these effects. Table 7-7 summarizes the results of this analysis, by benefit category.

These estimates are likely to understate the benefits of the proposed rule because they do not include several benefit categories that could not be monetized. Categories excluded from these estimates include ecological and recreational benefits from improvements in water quality, human health benefits associated with potential reductions in chronic effects resulting from ozone exposure, human health benefits associated with reductions in acute effects in attainment areas, agricultural benefits from reductions in emissions of ozone precursors in attainment areas,

TABLE 7-7

ANNUAL ECONOMIC BENEFITS FROM THE PROPOSED EFFLUENT GUIDELINES FOR THE PHARMACEUTICAL INDUSTRY (thousands of dollars)

Benefit Category	Estimated Economic Benefit ($1990)					
	Section 308 Data			Maximum Emissions Data/Section 308 Data*		
	Low	Average	High	Low	Average	High
Cancer Risk Reductions	$12	$96	$270	$210	$1,680	$4,725
Reductions in Emissions of Ozone Precursors:**						
Human Health Benefits+	$27	$857	$1,688	$27	$857	$1,688
Agricultural Benefits++	$163	$221	$276	$163	$221	$276
Environmental Benefits	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Benefits from Avoidance of Interference and Pass Through Problems and Improvements in Worker Health and Safety at POTWs	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Systemic Risk Reductions	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Total Benefits	$202	$1,174	$2,234	$400	$2,758	$6,689

* Cancer risk reduction benefits are based on the maximum emissions scenario data and other benefit estimates are based on the Section 308 data.

** Potential benefits associated with forest yield, materials damage, and visibility are not addressed in this analysis.

\+ The estimates presented only include benefits associated with reductions in acute health effects in nonattainment areas.

++ The estimates presented only include benefits associated with reductions in ozone precursor emissions in nonattainment areas.

benefits from avoided interference problems and improved worker health and safety at POTWs, and human health benefits from potential reductions in systemic risk.

SECTION EIGHT

COMPARISON OF BENEFITS TO COSTS

In this section, the estimate of the annual social costs of the regulation reported in Section Five is compared to the estimate of the total annual benefits.

Table 8-1 presents the annual benefits and annual costs of the selected regulatory options. Total social costs are $108.4 million and total quantifiable benefits range up to $7.0 million.

TABLE 8-1

COMPARISON OF ANNUAL BENEFITS AND COSTS FOR THE PHARMACEUTICAL RULEMAKING (in thousands of 1990 dollars)

■ **Benefits**	
— Cancer risk reductions	$12 - $4,725
— Reductions in emissions of ozone precursors Human health Agricultural benefits	 $27 - $1,688 $163 - $276
— Total quantifiable benefits	$202 - $6,689
■ **Costs**	
Total Annual Costs to Industry	$70,000
Total Annual Social Costs	$108,400

SECTION NINE

REFERENCES

Adams, Richard M. and J. David Glyer. 1988. "Assessment of the Agricultural Benefits of Tropospheric Ozone Reductions Using Office of Technology (OTA) Assumptions." Report prepared for the Office of Technology Assessment.

Carson, Richard T. and Robert Cameron Mitchell. 1988. "The Value of Clean Water: The Public's Willingness to Pay for Boatable, Fishable, and Swimmable Quality Water." Discussion Paper, Department of Economics, University of California, San Diego.

Desvousges, William H., V. Kerry Smith and Matthew P. McGivney. 1983. "A Comparison of Alternative Approaches for Estimating Recreation and Related Benefits of Water Quality Improvements." Report to the U.S. Environmental Protection Agency, Office of Policy Analysis.

Fisher, Ann, Lauraine G. Chestnut and Daniel M. Violette. 1989. "The Value of Reducing Risk of Death: A Note on New Evidence." Journal of Policy Analysis and Management 8(1): 88-100.

Fisher, Ann and Robert Raucher. 1984. "Intrinsic Benefits of Improved Water Quality: Conceptual and Empirical Perspectives." In: Advances in Applied Microeconomics, Volume 3, V. Kerry Smith and Ann D. Witte, eds., Greenwich, CT: JAI Press.

Freeman, A. Myrick III. 1993. The Measurement of Environmental and Resource Values, Theory and Methods. Washington, DC: Resources for the Future.

Krupnick, Alan J. and Raymond J. Kopp. 1988. "The Health and Agricultural Benefits of Reductions in Ambient Ozone in the United States." Resources for the Future, Discussion Paper QE88-10.

Krutilla, John V. 1967. "Conservation Reconsidered." American Economic Review 57:777-786.

National Acid Precipitation Assessment Program (NAPAP). 1989. Methods for Valuing Acidic Deposition and Air Pollution Effects. State-of-Science/Technology Report 27, Part B.

National Resource Council, Committee on Tropospheric Ozone Formation and Measurement. 1991. Rethinking the Ozone Problem in Urban and Regional Air Pollution. Washington DC: National Academy Press.

Neumann, James E. and Robert E. Unsworth. 1993. "Revisions to the Proposed Value of Life Methodology for the Section 812 Retrospective," memorandum to Jim DeMocker, Office of Policy Analysis and Review, Office of Air and Radiation, U.S. Environmental Protection Agency, from Industrial Economics, Incorporated.

Radian Corporation. 1993. "Summary of POTW Survey Responses." Memorandum to Frank Hund and Ed Terry, U.S. Environmental Protection Agency, Office of Water, Engineering and Analysis Division, from Kirsten Mahsman, Radian Corporation, 15 November.

Samples, Karl C. and Richard C. Bishop. 1985. "Estimating the Value of variations in Anglers' Success Rates: An Application of the Multiple-Site Travel Cost Method." Marine Resource Economics 2:(1):55-75.

Shortle, J.S., M. Phillips and J.W. Dunn. 1988. "Economic Assessment of Crop Damages Due to Air Pollution: The Role of Quality Effects." Environmental Pollution 53:377-385.

Unsworth, Robert E., James E. Neumann and W. Eric Browne. 1992. "Review of Existing Value of Life Estimates: Draft Valuation Document." Memorandum to Jim DeMocker, Office of Policy Analysis and Review, Office of Air and Radiation, U.S. Environmental Protection Agency, from Industrial Economics, Incorporated.

U.S. Congress, Office of Technology Assessment (OTA). 1989. "Catching our Breath: Next Steps for Reducing Urban Ozone." OTA-O-412, Washington, DC: U.S. Government Printing Office.

U.S. EPA. 1986. Report to Congress on the Discharge of Hazardous Waste to Publicly Owned Treatment Works. EPA 530-SW-86-004. February.

U.S. EPA. 1992. Development Document for Effluent Guidelines and Standards for the Pharmaceutical Point Source Category.

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

U.S. EPA. 1992. "Guidance to Protect POTW Workers from Toxic and Reactive Gases and Vapors."

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

U.S. EPA. 1994a. "The Costs and Benefits of Smoking Restrictions: An Assessment of the Smoke-Free Environment Act of 1993 (H.R. 3434)." Prepared at the request of Congressman Henry Waxman, Chairman, Subcommittee on Health and the Environment, Committee on Energy and Commerce. Office of Radiation and Indoor Air, Indoor Air Division.

U.S. EPA. 1994b. Air Quality: Revision to the Definition of Volatile Organic Compounds - Exclusion of Volatile Methyl Siloxanes and Parachlorobenzotrifluoride, 40 CFR Part 51, 59 FR 50693, October 5, 1994.

U.S. EPA. 1995a. Development Document for Proposed Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category. Office of Water, February.

U.S. EPA. 1995b. Economic Impact Analysis of Proposed Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Industry, February.

U.S. EPA. 1995c. Cost-Effectiveness Analysis of Proposed Effluent Limitations and Standards for the Pharmaceutical Manufacturing Industry, February.

U.S. Office of Management and Budget. 1989. Regulatory Impact Guidance. Appendix V of Regulatory Program of the United States Government, April 1, 1988 - March 31, 1989.

Versar, Inc., 1995. "Environmental Assessment of the Pharmaceutical Manufacturing Industry." Prepared for the U.S. Environmental Protection Agency, Office of Science and Technology, Standards and Applied Science Division, December.

Viscusi, W. Kip. 1992. Fatal Tradeoffs: Public and Private Responsibilities for Risk. New York: Oxford University Press.

_____. 1993. "The Value of Risks to Life and Health." Journal of Economic Literature 31:1912-1946.

Viscusi, W. Kip and W. Evans. 1990. "Utility Functions That Are Dependent on One's Health Status." American Economic Review. As cited in W. Kip Viscusi. 1992. Fatal Tradeoffs: Public and Private Responsibilities for Risk. New York: Oxford University Press.