

## **SECTION EIGHT**

### **OTHER SECONDARY IMPACTS**

This section presents the results of several analyses, including analyses investigating the impacts of the Final Pharmaceutical Industry Effluent Guidelines (separately and together with the impacts of the MACT standards rule) on trade and the balance of payments, on decisions of firms to relocate existing facilities to foreign countries (impact on decisions to locate new facilities in foreign countries is covered in Section Five), on POTWs through reductions in pollutant-loading-based revenues, and on distributional equity and environmental justice. Each of these analyses are discussed in detail in the sections below.

#### **8.1 ANALYSIS OF FOREIGN TRADE IMPACTS**

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

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

Sections 8.1.1 and 8.1.2 present the methodology used to estimate the change in the value of exports and evaluate the significance of this impact and the results of that analysis. Note that these impacts occur under the assumption that the pharmaceutical industry cannot or will not pass through costs to consumers, thus these impacts would reflect a decision on the part of the industry to absorb all costs of compliance and

thus would experience no price disadvantages in the international market. Section 8.2 investigates whether firms or facilities are likely to relocate to foreign countries due to the effluent guidelines and in that way affect the balance of trade.

### **8.1.1 Methodology**

For facilities expected to close and that exported a portion of their pharmaceutical production in 1990, the value of 1990 pharmaceutical exports is estimated. The estimate for each facility is obtained directly from survey data: the total value of pharmaceutical shipments reported by the facility is multiplied by the percentage of pharmaceutical shipments exported, and these values are summed across closing facilities to obtain an estimate of the total value of U.S. pharmaceutical exports no longer produced. This value is then compared to the total value of U.S. pharmaceutical exports produced in 1990. The analysis assumes that none of the decreased production of exported pharmaceutical products is replaced by alternative U.S. products. This “worst-case” assumption is very conservative and is likely to overestimate the reduction in exports. If the impact on foreign trade is not significant in this worst-case scenario, then more realistic scenarios would also indicate no significant impacts. Likewise, increases in imports are assumed to be equivalent to the decline in exports (consistent with the zero cost-passthrough assumption used in the facility- and firm-level impact models). The existing balance of trade is then adjusted to reflect the increase in the value of imports and decline in the value of exports. A comparison of pre-and post-regulation trade balances will reveal the extent of the regulation’s impact on the U.S. balance of trade.

### **8.1.2 Results**

The impact of effluent guidelines on pharmaceutical exports and the U.S. balance of trade is negligible. As discussed in Section Five and Section Six, one facility is expected to close as a result of the selected options (under Baseline 3 only) and one single-facility firm is expected to close and fail. Neither of these facilities export any pharmaceutical products, thus EPA anticipates no impact from closures/failures on

the \$5.7 billion (1991) total pharmaceutical industry exports.<sup>1</sup> Table 8-1 presents the results of this analysis. Note that no baseline analysis is performed because EPA expects no closure of facilities in the baseline.

## **8.2 EFFECTS ON PROFIT MARGINS AND THE LIKELIHOOD OF FOREIGN RELOCATIONS**

EPA investigated baseline and postcompliance profit margins among the firms affected by the Final Pharmaceutical Industry Effluent Guidelines (including MACT standards impacts) to determine whether impacts on profitability might exert pressure on firms to relocate to foreign countries. A measure of impact on a firm is the extent to which profit margins are affected (although clearly this effect is not of the magnitude associated with closures and failures). Furthermore, it might be argued that firms with the means to relocate themselves or their facilities to foreign countries where environmental requirements might be less stringent might do so in response to a potential profit margin “squeeze.” The detailed methodology and results of a profit margin analysis are presented below in Sections 8.2.1 and 8.2.2.

### **8.2.1 Methodology**

EPA uses posttax EBIT (earnings before interest and taxes) divided by revenues as the measure of profit margin. The Agency uses posttax EBIT to allow for the different means by which various firms finance their capital, as recommended by Brealey and Meyers.<sup>2</sup> Only firms in the postcompliance analysis that do not fail postcompliance are analyzed here (baseline failures are dropped from the analysis; postcompliance failures also are dropped to avoid double counting impacts). EPA investigated median profit margins in each of the baselines and postcompliance relative to the three baselines. EPA also individually assessed firms where profit margins are expected to drop by more than 10 percent (for example where a 5 percent profit margin drops to below 4.5 percent). This assessment includes not only by how much profit margins drop, but the means these firms might have to relocate. Relocation to foreign countries entails not

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<sup>1</sup> U.S. Department of Commerce. 1993. *U.S. Industrial Outlook: 1993*. Washington, DC: U.S. Government Printing Office.

<sup>2</sup> Brealey, Richard A., and Myers, Stewart C. 1996. *Principles of Corporate Finance*, Sixth Edition. New York: McGraw-Hill.

**Table 8-1**

**Loss in Foreign Shipments for Selected Options  
(1990 dollars)  
Postcompliance Analysis**

<b>Facility Subcategory</b>	<b>Exports Lost</b>	<b>Total Exports *</b>	<b>Percent of Total</b>
<b>Direct Discharge</b>			
A/C	\$0	\$695	0%
B/D	\$0	\$9,174,487	0%
<b>Indirect Discharge</b>			
A/C	\$0	\$478,207,957	0%
B/D	\$0	\$447,853,303	0%
<b>Zero Discharge</b>			
A/C	\$0	\$2,444,418	0%
B/D	\$0	\$845,906	0%
<b>All Facilities</b>			
<b>TOTAL</b>	<b>\$0</b>	<b>\$938,527,152</b>	<b>0%</b>

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

Note:

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

Source: Section 308 Survey Data and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

only the means to physically move location, but the means to afford the transaction costs of relocating to a country if a firm currently has no operating experience there. Language and cultural barriers can effectively prevent small firms with limited resources from relocating. Total shipments of any firms likely to relocate are assessed against total exports, both in the affected industry and the broader pharmaceutical industry. EPA also assesses the impact of trade agreements and other barriers to a cheaper operation outside the environmental controls imposed by the United States that might further discourage relocation.

### **8.2.2 Results**

Table 8-2 shows the median and ranges of aftertax profit margins under each of the three baselines after the costs of the effluent guidelines are considered and assuming no costs can be passed through to consumers. As the table shows, the median aftertax profit margin is a healthy 7.59 percent in Baseline 1. The median does not vary across all three baselines and across all three postcompliance scenarios. At most, from Baseline 1 through Postcompliance Scenario 3 (postcompliance against Baseline 3, which includes MACT standards costs), the median profit margin drops from 7.59 to 7.53 percent. Of course, individual firms can experience larger impacts than medians might suggest, so EPA also investigated the numbers of firms that might experience a reduction in profit margin of more than 10 percent (see Table 8-3 and Table 8-4). Table 8-3 presents the baseline profit margins by size of profit margins. As the table shows, many firms (over 50 percent, regardless of baseline) have profit margins in the range above 7 percent. The vast majority of these firms show nearly no impact throughout all baselines and postcompliance. Another 20 to 21 percent (depending on baseline) have profit margins in the 4 to 7 percent range. A further 13 to 14 percent have profit margins in the 2 to 4 percent range. Only 12 to 13 percent have profit margins in the less than 2 percent range either before or after compliance with the Final Pharmaceutical Industry Effluent Guidelines. Neither the Final Pharmaceutical Industry Effluent Guidelines nor the MACT standards rule appear to have very noticeable impacts on these ranges.

Table 8-4 investigates the more highly affected firms. EPA individually evaluated firms showing large changes in profit margins, defined here as a change in profit margin greater than 10 percent (calculated as a percent change in the percentage). As Table 8-4 shows, eight firms will have a change in profit margin of greater than 10 percent (one additional firm experiences a change greater than 10 percent postcompliance relative to Baseline 3). These firms therefore comprise a group of firms that will experience some impacts

**Table 8-2**

**Profit Margin Median and Range for Firms Affected  
by the Final Pharmaceutical Industry Effluent Guidelines**

	Median	Range	
		Minimum	Maximum
Baseline 1	7.59%	-54.01%	77.40%
Baseline 2	7.59%	-54.01%	77.40%
Baseline 3	7.59%	-54.19%	77.40%
Postcompliance 1	7.53%	-54.01%	77.40%
Postcompliance 2	7.53%	-54.01%	77.40%
Postcompliance 3	7.53%	-54.19%	77.40%

Source: Section 308 Survey Data and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

**Table 8-3**

**Baseline and Postcompliance Profit Margins \***

Profit Margin	Baseline 1				Baseline 2				Baseline 3			
	Baseline		Postcompliance		Baseline		Postcompliance		Baseline		Postcompliance	
	Number of Firms	Percent of Total										
< 0%	9	7.0%	9	7.0%	9	7.0%	9	7.0%	9	7.0%	9	7.0%
0 - 1%	3	2.3%	3	2.3%	3	2.3%	3	2.3%	3	2.3%	3	2.3%
>1 - 2%	4	3.1%	4	3.1%	4	3.1%	4	3.1%	5	3.9%	5	3.9%
>2 - 4%	16	12.5%	17	13.3%	16	12.5%	17	13.3%	17	13.3%	18	14.1%
>4 - 7%	27	21.1%	27	21.1%	27	21.1%	27	21.1%	25	19.5%	25	19.5%
>7%	69	53.9%	68	53.1%	69	53.9%	68	53.1%	69	53.9%	68	53.1%
Total	128	100.0%	128	100.0%	128	100.0%	128	100.0%	128	100.0%	128	100.0%

\* Out of firms in the postcompliance analysis.

Source: Section 308 Survey Data and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

**Table 8-4**

**Percentage Reduction in Profit Margin due to the Pharmaceutical Effluent Guidelines**

Profit Margin	Total	Percentage Reduction in Profit Margin									
		0 - <5%		5 - <10%		10 - <20%		20 - <50%		>= 50%	
		Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
<7% Baseline profit margin	59	48	84.1%	4	6.8%	2	3.4%	2	3.4%	3	5.1%
>7% Baseline profit margin	69	66	95.7%	2	2.9%	1	1.4%	0	0.0%	0	0.0%
<7% Baseline profit margin	59	48	81.4%	4	6.8%	2	3.4%	2	3.4%	3	5.1%
>7% Baseline profit margin	69	66	95.7%	2	2.9%	1	1.4%	0	0.0%	0	0.0%
<7% Baseline profit margin	59	48	81.4%	3	5.1%	3	5.1%	2	3.4%	3	5.1%
>7% Baseline profit margin	69	66	95.7%	2	2.9%	1	1.4%	0	0.0%	0	0.0%

\* Measured as (Postcompliance profit margin (%) - Baseline profit margin(%)) / Baseline profit margin (%).

Source: Section 308 Survey Data and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

short of firm failure as a result of the effluent guidelines (Table 8-5). A total of two of these nine firms also are counted as having some impacts in the indeterminate analysis in Section Six. The total number of distinct firms in both analyses sum to 14.

Furthermore, these nine firms may have the greatest motivation for relocating facilities outside the United States. EPA addresses these issues and investigates whether, even if the motive is there, the means are available to undertake a relocation.

As Table 8-5 shows, most of these firms are not likely to experience a large absolute change in profit margin (measured as baseline profit margin minus postcompliance profit margin). Only firm 8, which drops from a 12.16 percent profit margin to a 9.90 percent profit margin under Baseline 3 (note that this firm also appears as an affected firm in the indeterminate analysis), is appreciably affected under the three baselines. Six of the remaining firms' profit margins drop, in absolute (not percentage) terms, less than 1 percent. Two additional firms show a drop greater than 0.5 percent in absolute terms. When the leap from Baseline 1 to Postcompliance Scenario 3 is considered (the maximum impact from the combined rules), three firms experience an absolute drop in profit margins of more than 1 percent, with an additional three firms showing an absolute drop of more than 0.5 percent.

Many of these firms with large percentage and absolute drops in profit margin are unlikely to have the means to undertake a foreign relocation. The median assets of the group of 9 firms is \$12.5 million, median working capital is \$4.5 million, and median total equity is \$7.6 million. Furthermore, the median foreign shipments value is \$95,500 and the median percentage of foreign shipments to total shipments is 2 percent. Thus, this group is generally composed of small firms with little to no experience with foreign markets. The two largest firms (in terms of assets) in this group, that might be more able to find the means to relocate, have the smallest absolute change in profit margins (0.30 percent and 0.43 percent), which might limit their motivation to relocate, even though on a percentage change basis, the change is about 10 percent for both.

Several factors other than means and motivation might limit any incentive to relocate. First, many foreign countries, either on their own, or as a result of trade agreements such as the North American Free Trade Agreement, are becoming more aggressive with environmental controls. It is likely that where relocation might make sense (for example, close to major market areas such as Europe or the Far East) firms

**Table 8-5**

**Profit Margins of Firms Showing Some Impact Short of Firm Failure**

Firm ID	Baseline 1			Baseline 2			Baseline 3		
	Baseline Profit Margin	Postcompliance Profit Margin	Percent Change	Baseline Profit Margin	Postcompliance Profit Margin	Percent Change	Baseline Profit Margin	Postcompliance Profit Margin	Percent Change
1	5.01%	3.04%	-39.28%	5.01%	3.04%	-39.28%	5.01%	3.04%	-39.28%
2	2.73%	2.43%	-11.08%	2.73%	2.43%	-11.08%	2.64%	2.34%	-11.46%
3	0.88%	0.33%	-62.98%	0.88%	0.33%	-62.98%	0.88%	0.33%	-62.98%
4	-5.29%	-6.20%	-17.32%	-5.29%	-6.20%	-17.32%	-5.29%	-6.20%	-17.32%
5	4.70%	4.27%	-9.31%	4.70%	4.27%	-9.31%	3.81%	3.38%	-11.47%
6	12.16%	9.90%	-18.58%	12.16%	9.90%	-18.58%	11.89%	9.63%	-19.00%
7	3.99%	2.14%	-46.48%	3.99%	2.14%	-46.48%	3.99%	2.14%	-46.48%
8	-0.24%	-0.60%	-155.26%	-0.24%	-0.60%	-155.26%	-0.24%	-0.60%	-155.26%
9	0.82%	0.25%	-69.15%	0.82%	0.25%	-69.15%	0.79%	0.23%	-71.18%

Source: Section 308 Survey Data and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

may be faced, or may soon be faced, with some of the same environmental control issues, and these controls might be even more expensive outside of the United States (for example, if pollution control equipment must be imported from the United States, transportation costs alone would make pollution control equipment more expensive).

Despite the general lack of motivation and the potential lack of means and other barriers to relocation discussed above, some firms might consider relocating facilities. If the ten firms identified above, which have perhaps the greater motivation to relocate, were to relocate their facilities, the impact on the balance of trade can be represented by the total domestic and international shipments of pharmaceuticals by these firms. These domestic and international shipments combined total \$263.7 million, of which only about \$4 million are international shipments. The potential for loss in foreign shipment is only 0.001 percent of the \$305 billion of all foreign shipments by the U. S. in 1991, and the potential for increase in imports is only 0.04 percent of the \$732 billion in imports in 1991.<sup>3</sup> Thus, even in the very unlikely event that these firms do relocate some or all of their pharmaceutical facilities, the impacts on trade and the balance of payments are negligible.

### **8.3 IMPACTS ON POTWS**

Comments on the proposed rule raised the possibility that if pharmaceutical facilities no longer send the same level of pollutant loadings to POTWs, revenues to POTWs could suffer. According to EPA's development document, however, EPA is promulgating pretreatment standards for 24 volatile organic compounds for all subcategories and ammonia for subcategories A and C. The Agency expects that the reduction in the BOD discharged to POTWs as the result of compliance with PSES for these pollutants to be minimal. As a result, EPA believes that any reduction in revenue to POTWs that charge industrial users, subject to PSES, will be insignificant. Since many of these pollutants are highly volatile and are volatilized in the POTWs' primary units before they can be biodegraded, EPA believes that the final PSES should not have any substantial effect on the variable operating costs of POTWs as well.

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<sup>3</sup> U.S. Bureau of the Census. 1997. *Statistical Abstract of the United States*. Washington, DC: U.S. Government Printing Office.

Even if BOD loads to POTWs were to drop substantially, there are a number of mitigating factors to consider. First, the numbers of POTWs that receive a large portion of their flow from pharmaceutical facilities must be determined. Second, the way in which POTWs set their fees must be considered. Third, even if a POTW receives a large portion of flow from affected pharmaceutical facilities, and it sets fees on the basis of pollutant loadings or concentrations rather than raw volume, effects on both revenues and costs must be considered. These issues and supporting analyses are discussed below.

### **8.3.1 Methodology**

EPA investigated the prevalence of POTWs with a large proportion (10 percent of industrial flow or more) of flow received from pharmaceutical firms. In 1988, the Agency undertook the National Sewage Sludge Survey, which asked, among other things, the amount of flow from various types of industries to the respondent POTWs. This statistically valid survey of the universe of POTWs operating secondary and above treatment processes, although somewhat dated, should still provide a reasonable estimate of the prevalence of POTWs with a high percentage of flow from the pharmaceutical industry.

The other two considerations—how many POTWs set rates on the basis of pollutant loadings or concentrations, and impacts on costs—are addressed qualitatively in the results section below.

### **8.3.2 Results**

Using the National Sewage Sludge Survey, EPA determined that only a few POTWs received more than 10 percent of their industrial flow from pharmaceutical facilities in 1988. Table 8-6 presents the results of EPA's search for potentially highly affected POTWs.<sup>4</sup> In all other cases, pharmaceutical flow is less than 10 percent of total industrial flow. It is important to note that the six POTWs listed here statistically represent about 45 POTWs nationwide. In particular, Rochester and Wade Hampton are statistically representative of

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<sup>4</sup> None of the information in the NSSS is CBI, since these are publicly owned entities.

**Table 8-6**

**POTWs With Substantial Pharmaceutical Wastewater Flow  
(>10 percent of total industrial flow)**

<b>Survey ID</b>	<b>POTW Name</b>	<b>POTW Authority</b>	<b>Percentage of Industrial Flow Attributed to Pharmaceutical Industry</b>	<b>Percentage of Total Revenues Attributable to Industry User Fees</b>
35-23-207	Rochester STP*	City of Rochester, MI	51.76%	97.45%
16-32-263	Passaic Valley Treatment Plant	Passaic Valley Sewerage, Newark, NJ	14.07%	27.47%
33-35-303	Orangetown DPW*	Town of Orangetown, NY	56.25%	25.20%
35-42-389	Wade Hampton Plant	WCRSA, Greenville, SC	35.82%	24.97%
26-32-267	Rahway Valley STP	Rahway Valley, NJ	41.51%	15.75%
24-15-104	NSSD-Clavely Rd. STP	North Shore SD, Gurnee, IL	13.97%	14.18%

\*Pharmaceutical flow is also 27 percent (Rochester) and 21 percent (Orangetown) of total flow (not just industrial flow)

Source: U.S. EPA, 1988 National Sewage Sludge Survey.

20 POTWs each. (Passaic, Rahway, and NSSD represent themselves only, and Orangetown represents two POTWs, statistically).<sup>5</sup>

It is possible that among these 45 POTWs, the pharmaceutical industry might contribute a sizeable amount to POTW revenues, but the way in which these POTWs set rates also needs to be considered. Generally, POTWs might set rates by total volume of flow, by amount of pollutants load (for example, on the basis of BOD or some other pollutant), or on the basis of flow at or above a certain pollutant concentration. POTWs also might mix these rate setting strategies. For example one rate might be set for volume, with a surcharge for volume over a certain BOD concentration. Only POTWs where the major portion of the fee collected from the user is set on the basis of pollutant concentration or load would see a marked decline in revenues if pollutant loads or concentrations dropped substantially.

On the other hand, reductions in pollutant loads or concentrations from users often result in measurable costs savings. A portion of a POTW's variable costs depends on the load handled by the facility. For example, higher BOD content may require greater power usage stemming from the greater need for aeration to keep the wastewater and sewage sludge treatment processes aerobic, if an aerobic process is used. Higher TSS levels result in larger amounts of sewage sludge generated, with higher costs of disposal. Higher concentrations of pollutants can also lead to a greater need for treatment chemicals such as coagulants or clarifying chemicals. So even if the POTW loses some revenues, it saves some costs.

Even if revenue losses exceed costs savings, POTWs will, one way or another, pass through these impacts to their users. Most of the POTWs that are at all likely to be affected by potential reductions in loads from pharmaceutical firms are located in urban areas and are likely to have large numbers of users over which to spread any fee increases or other costs. By the time the revenue losses are translated to a cost-per-user basis, any small impact from the effluent guidelines will be difficult to measure. For example, the entire \$245,000 loss of revenues that the commenter estimated would occur at Passaic Valley would amount to

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<sup>5</sup> Presented in this table is one of the POTWs cited in the comments to the proposal, Passaic Valley. Note that although the commenter argues that losses in revenues to Passaic will be \$254,000, the commenter does not note Passaic's annual revenues. In 1988, these revenues totaled about \$56 million, so this loss, if it occurred, would amount to only 0.45 percent of Passaic's revenues (assuming revenues have remained constant over the intervening years).

almost nothing on a per-user basis, if it materialized at all, given that some costs savings might be experienced and given the huge number of users in Newark, NJ, and its environs.

Thus EPA concludes that (1) impacts on BOD levels will be minimal, (2) relatively few POTWs will be potentially affected even if BOD or other pollutant loads or concentrations are reduced substantially, (3) fewer still are likely to have rate structures sensitive to declines in pollutant loads or concentrations, (4) some of these will experience costs savings of, perhaps, a similar magnitude, (5) where a noticeable difference between revenues lost and costs savings occurs, an impact directly on the POTW will probably not occur, since impacts will be passed to users, and (6) any impacts on users, once spread over many users, will be negligible.

## **8.4 DISTRIBUTIONAL EQUITY AND ENVIRONMENTAL JUSTICE**

### **8.4.1 Analysis of Distributional Impacts**

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

Conversely, the assumption that facilities will bear the entire cost of incremental regulatory costs might understate the economic impacts on consumers of pharmaceuticals. If the more realistic assumption that manufacturers will raise pharmaceutical prices in response to increased regulatory costs is employed, then one needs to consider who will be affected by these price increases and whether high drug prices will affect certain demographic groups more than others. For example, the elderly account for a very large portion of all drug use. This group, therefore, might be particularly hard hit by increases in drug prices. It might be reasonable to assume that the uninsured population will also be particularly hard hit by increases in drug

prices because they have no immediate financial recourse and might have to make difficult decisions between pharmaceuticals and other daily necessities. Ultimately, state and federal governments might bear the costs of increased drug prices through Medicaid, Medicare, and other health insurance programs.

This section first investigates the extent to which drug prices could rise assuming perfectly inelastic demand. Given perfectly inelastic demand, the EA calculates the rise in drug prices as the ratio of total compliance costs to total cost of pharmaceutical production in the affected facilities (e.g., if compliance costs are 1 percent of pharmaceutical production costs, then drug prices of all drugs at the affected facilities are assumed to rise by 1 percent). The analysis then investigates the impacts of increased drug prices on various demographic groups such as the elderly, the population living under the poverty level, disadvantaged minorities, the uninsured, and state and federal governments. In the absence of any quantitative data on price elasticities and existing drug prices, the discussion is necessarily qualitative in nature. The discussion assumes that pharmaceutical manufacturers are able to pass through all of the increased regulatory costs associated with the various waste water treatment options, including all MACT costs, where they occur.

#### **8.4.2 Increases in Drug Prices**

Table 8-7 shows compliance costs (including costs of the MACT standards rule), as a percentage of total pharmaceutical costs by regulatory option. The average (median) ratio for each subcategory (calculated on a facility-by-facility ratio basis) ranges from 0.002 to 0.3 percent. For all the selected regulatory options combined, the median ratio of compliance costs to total pharmaceutical costs by facility is approximately 0.01 percent. Table 8-7 also shows the distribution of the number of facilities by compliance costs to pharmaceutical costs. As can be seen, 31 facilities (12 percent of all facilities in this analysis) would incur compliance costs greater than 1 percent but less than 10 percent of total pharmaceutical production costs, and seven facilities (3 percent of all facilities) would incur compliance costs greater than 10 percent of total pharmaceutical costs under the selected options (including MACT standards costs). One quarter of all facilities would experience no increase in total pharmaceutical production costs as a result of the effluent guidelines plus MACT standards costs.

Reliable data on total U.S. pharmaceutical production costs are not available. Thus, the EA cannot precisely compute compliance costs as a percentage of total U.S. pharmaceutical production costs.

**Table 8-7**

**Compliance Costs as a Percentage of  
Total Pharmaceutical Production Costs, by Facility  
(includes MACT standards costs)**

Regulatory Option	Compliance Costs/Total Costs										
	0.0%		>0.0% - 0.1%		>0.1% - 1.0%		>1.0% - 10.0%		>10%		Median Ratio
	Number of Facilities	Percent of Total	Number of Facilities	Percent of Total	Number of Facilities	Percent of Total	Number of Facilities	Percent of Total	Number of Facilities	Percent of Total	
<b>Selected Options</b>											
BAT-A/C (with BPT)	1	7%	2	14%	6	43%	4	29%	1	7%	0.191%
BPT-B/D only	3	33%	1	0%	4	44%	0	0%	0	0%	0.034%
PSES-A/C	8	9%	18	21%	13	15%	19	22%	4	5%	0.295%
PSES-B/D	38	25%	59	39%	11	7%	8	5%	2	1%	0.002%
<b>All Facilities</b>											
All	50	19%	80	31%	34	13%	31	12%	7	3%	0.009%

Note:

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

Source: Section 308 Survey Data and the Pharmaceutical Industry Facility and Firm Model, EPA, 1998.

Nevertheless, it is clear that if worst-case compliance costs average 0.01 percent of the total pharmaceutical production costs of the regulated sector, this ratio would be significantly lower if compliance costs were compared to pharmaceutical production costs for the entire industry.

### **8.4.3 Impacts on Specific Demographic Groups**

Although in the aggregate, the potential overall increase in drug prices attributable to increased regulatory costs is minuscule, the potential increase in specific drug prices might have a significant impact on certain demographic groups. As noted above, seven facilities will experience compliance costs in excess of 10 percent of total pharmaceutical manufacturing costs. If the drugs produced by these facilities are unique (i.e., protected from direct competition either through patents or a lack of close substitutes) then these facilities might be able to increase the price of their drugs in order to offset compliance costs. Table 8-8 presents the result of an examination of the products produced by facilities that incur compliance costs greater than 10 percent of total pharmaceutical production costs and presents which groups predominantly use the types of products made at these facilities. A total of 40 products were identified as products potentially subject to substantial price increases out of a total of more than 110,000 pharmaceutical products manufactured each year.<sup>6</sup>

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

As Table 8-8 shows, children (including infant and adolescents), women, and the elderly are likely to be the major consumers of many of these products. According to Health Insurance Association of America,<sup>7</sup> the groups least likely to have health insurance are Hispanics (31.2 percent of whom lack health insurance), young adults 16-24 years of age (20.5 percent of whom lack health insurance), and African Americans (17.5 percent of whom lack health insurance); African Americans, Hispanics, and children are most likely to be

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<sup>6</sup> As cited in RTI, 1993. *Economic Analysis of Effluent Guidelines Regulations for the Pharmaceutical Industry*. Draft Report. Contract No. 68-C8-0084. Research Triangle Park, NC: RTI.

<sup>7</sup> Health Insurance Association of America, 1991. *Source Book of Health Insurance Data*.

**Table 8-8**

**Disproportionate Users of Potentially Highly Affected Products**

	<b>Total Numbers of Affected Products</b>	<b>Infants, Children, or Adolescents</b>	<b>The Elderly</b>	<b>Young Adults/Adult Women</b>	<b>Middle- Aged Women</b>	<b>African- Americans</b>	<b>Other</b>	<b>Unknown</b>
Number of Products	40	15	28	13	4	3	3	18
Percentage of All Affected Products	100%	38%	70%	33%	10%	8%	8%	45%

Source: Overton, V., and A. Desilets. Demographics of the Major Users of Selected Drugs. Memorandum dated June 18, 1998 (confidential business information).

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

covered by government insurance, and African Americans, Hispanics, and the elderly are least likely to have insurance related to employment. Government insurance programs tend to spend less on drugs and other medical nondurables than do private insurers, according to the same source, and about 93 percent of people with work-related medical insurance have some type of drug insurance.

When all these factors are accounted for, it appears that those who lack any health insurance, those who are covered by government insurance, and those who are covered by nonwork-related medical insurance might be least likely to have drug coverage. This group would include: Hispanics, African Americans, the elderly, young adults (16-34), and children (under 16). When the predominant consumers of the products expected to be affected by potentially sizeable price increases are compared to the groups most likely to lack drug insurance, young adult women, children, and the elderly are likely to be the most affected by potential price increases, if such increases can be passed through to consumers.

Because, on average, any potential price increases are likely to be very low (0.01 percent on average), impacts on mass consumers of drugs such as HMOs, governments, and, indirectly, third-party insurers, should be minimal.

#### **8.4.4 Environmental Justice**

Impacts on environmental justice should be minimal. As noted above, any price increases on drugs will be very small, and impacts on disadvantaged groups such as the poor and certain minority groups will be minimal. Furthermore, many of these groups will benefit from the Final Pharmaceutical Industry Effluent Guidelines. The benefits of the Final Pharmaceutical Industry Effluent Guidelines, discussed more fully in Section Ten, are expected to be widely dispersed, and will include recreational anglers, POTWs, and thus the general public, and persons consuming fish from the reaches of surface water affected by pharmaceutical effluent. Since the persons most likely to benefit from lower levels of contaminants in fish tend to be subsistence anglers, not recreational anglers, these benefits might accrue to persons in lower socioeconomic groups and/or Native Americans. Also, since children of subsistence anglers are likely to be the most vulnerable of all these groups to any pollutants taken up by fish, this is another group most likely to accrue health benefits.

A large number of the surveyed pharmaceutical facilities (10.5 percent) are located in Puerto Rico, which is substantially poorer than the United States as a whole. The per capita income of Puerto Rico is \$7,009 (\$1993), in contrast to the lowest U.S. per capita income, by state, of \$14,475 (\$1993) for Mississippi.<sup>8</sup> The regulation of the pharmaceutical industry will result in a cleaner environment, both water and air, which will directly benefit all persons, but the greatest benefit might accrue to lower socioeconomic groups that often live near major urban manufacturing facilities such as those regulated by the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule.

Thus many of those who might bear the costs of the regulation (however small), including children and those in lower socioeconomic groups, might also be those who gain the most benefit from the Final Pharmaceutical Industry Effluent Guidelines and the MACT standards rule.

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<sup>8</sup>Per capita income sources: <http://www.pr-eda.com> and <http://www.census.gov>