

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

(v) **Projected Impacts on Small Firms.** Projected 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 in the post-compliance analysis.

When cash flow is analyzed, however, impacts seem less disproportionate. Except in the 19 to 99 employees group, 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 small firms (or all large 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.

7. Projected Distributional Impacts

a. Impacts on Drug Prices. Assuming that all costs are passed on to consumers and that price increases will reflect 100 percent of the cost increases to manufacturers, the following observations can be made. For all the selected regulatory options, the ratio of compliance costs to total pharmaceutical costs was 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.

b. Impacts on Specific Demographic Groups. 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.

8. Projected Impacts on New Sources

The projected 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 \$39,000 to a \$674,000 difference (1994 \$) (for A/C direct dischargers), depending on the type of facility. The maximum \$674,000 difference generates the highest percentage of compliance cost differential to pharmaceuticals manufacturing cost—about 1.4 percent

of total manufacturing costs and about 3.0 percent of pharmaceutical manufacturing costs. Since this cost differential is likely to be less than that assumed here, this small premium estimated to be paid by new sources is not likely to have much impact on the decision to enter the market. Furthermore, these same options, when applied to existing sources, were found to have nearly identical impacts on existing sources as the selected options for existing sources. Thus no significant barriers to entry are estimated to result from the proposed new source requirements.

9. Regulatory Impact Assessment

The Agency has prepared a regulatory impact assessment (RIA) for the proposed regulatory alternative. The RIA responds to the requirements in Executive Order 12866 to assess both the costs and benefits to society of significant regulatory actions. Significant regulatory actions are those that impose an annual cost to the economy of \$100 million or more, or have certain other regulatory, policy or economic impacts. The RIA is detailed in "Regulatory Impact Assessment of the Proposed Effluent Guidelines for the Pharmaceutical Manufacturing Industry" (see Section II for availability of this and other supporting documents). This RIA was submitted to OMB for review as required by Executive Order 12866.

The RIA analyzes the effects of current air and water emissions and assesses the benefits of reductions in these emissions resulting from the proposed regulation. EPA expects a variety of human health, environmental, and economic benefits to result from these reductions in effluent loadings and air 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; human health benefits due to reductions in non-carcinogenic risk; ecological and recreational benefits due to improved water quality; and benefits to publicly owned treatment works (POTWs) from reductions in interference, pass through, and sludge contamination problems and improvements in worker health and safety. EPA monetizes the estimated benefits for reductions in air emissions of ozone precursors and cancer risk reductions, but is unable to quantify the dollar magnitude of benefits from the other benefit categories. Air benefits are estimated separately for Section 308