experience significant impacts (i.e., firm failure) as a result of implementing the selected regulatory options. In addition, only two firms with indirect discharging facilities with subcategory A and C operations and one firm owning an indirect discharging facility with subcategory B and D operations would be expected to experience significant impacts as a result of compliance costs. Thus, a total of three firms are projected

to fail under the conservative assumption of no costs being passed through to consumers. Overall, these firms represent 3.8 percent of all firms with indirect discharging facilities with subcategory A and C operations, 1.4 percent of firms with subcategory B and D operations, and 2.3 percent of all regulated firms. As indicated by the Profitability Analysis, 15 firms (11 percent of firms in the postcompliance

analysis) are anticipated to have major impacts short of firm failure (i.e., will experience a change in ROA of greater than 5 percent). Impacts are most likely overstated, however, because this analysis assumes that firms cannot pass any increased costs through to consumers. If half the costs can be passed through to consumers there would be no firm failures.

TABLE XI.B.3.b2-1.—PROJECTED FIRM FAILURE: 1 POST COMPLIANCE ANALYSIS 2

	Total No. of firms	Regulatory impact on firms			
		No significant impact		Significant impact	
		No.	Percent	No.	Percent
Firms with A/C Direct Facilities	15 7	15 7	100.0 100.0	0	0.0
Firms with A/C Indirect Facilities Firms with B/D Indirect Facilities	53 72	51 71	96.2 98.6	2	3.8 1.4
All Firms <sup>3</sup>	133	130	97.7	3	2.3

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

<sup>1</sup>Firm failure is defined when a firm's return on assets or interest coverage ratio falls below industry benchmarks. This analysis assumes no costs can be passed through to consumers.

<sup>2</sup>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.

<sup>3</sup>Number of firms for All Firms may 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.

## 4. Projected Employment Losses and Gains and Community-Level Economic Impacts

Based on facility closures and firm failures, the employment losses analysis sums the number of jobs lost in the postcompliance scenario and compares these losses to community employment measures. Job gains are calculated based on the cost of manufacturing, installing, and operating compliance equipment.

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 indirect discharging facilities with subcategory A and C operations and 13 FTEs among indirect discharging facilities with subcategory B and D operations, for a total of 91 FTEs or 0.07 percent of total employment for the affected portion of the industry. Secondary employment 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.

Employment losses are offset to some extent by the need to hire workers to manufacture, install, and maintain the pollution control equipment. Primary employment gains are expected to total 68 annual FTEs for manufacturing

equipment, 10 annual FTEs for installing equipment, and 0 to 889 annual FTEs for operating and maintaining equipment for a total of 78 to 967 annual FTE gains. The sum of primary and secondary 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. Projected Foreign Trade Impacts

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 had pharmaceutical exports totaling \$0.09 million (1994 \$). The loss of these exports would have virtually no effect on U.S. pharmaceutical exports, which, according to the U.S. Department of Commerce, totalled \$5.7 billion in 1991.

## 6. Regulatory Flexibility Analysis

a. Purpose of the Regulatory
Flexibility Analysis. The Regulatory
Flexibility Act requires the federal
government to consider the impacts on
small entities as part of rulemaking
procedures. The goal of the analysis is
to ensure that small entities potentially
affected by a new regulation will not be
disproportionately burdened. Small
entities have limited resources, and it is
the responsibility of the regulating

federal agency to avoid, if possible, disproportionately or unnecessarily burdening such entities.

b. Projected Impacts on Small Businesses. (i) Size Distribution. Small firms make up 76 percent of the 190 firms in the survey universe. The largest percentage of firms are in the 100 to 499 employees size group (37 percent of all firms in the survey universe).

(ii) Recordkeeping and Reporting Requirements. The proposed effluent guidelines for the pharmaceutical industry are revisions to existing effluent guidelines and, accordingly, most of the recordkeeping and reporting requirements to which the industry would be subject are not new requirements. There are some new monitoring requirements. The new monitoring costs total \$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 the new monitoring costs (61 percent of total monitoring costs).

(iii) Other Federal Requirements. EPA is aware of no federal rules that duplicate, overlap, or conflict with the proposed effluent guidelines for the pharmaceutical industry.

(iv) Significant Alternatives to the Proposed Rule. No significant alternatives to the proposed rule will substantially reduce impacts on small entities, thus the Agency believes the