Annual Report of the Chief Counsel for Advocacy on Implementation of the Regulatory Flexibility Act, Calendar Year 1998

Office of Advocacy
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To the President and Congress of the United States:

For the past five years, as Chief Counsel for Advocacy at the U.S. Small Business Administration, I have been reporting to you on agency compliance with the Regulatory Flexibility Act of 1980 (RFA). This law requires federal agencies to consider the effects of their regulatory actions on small businesses and other small entities and to minimize any undue burden. I am pleased, once again, to be submitting this report on activities undertaken by the Office of Advocacy in calendar year 1998 to advance compliance with the RFA.

Summary – 1998 Activities
In 1998, the Office of Advocacy reviewed an estimated 1,600 proposed, interim, and final rules for their small business impacts. These reviews involved regulations affecting a wide range of industries. The regulations, in many instances, would not attract media attention but the regulations are nevertheless important because of their significant impacts on small entities.

But the number of regulations reviewed is not as important as the issues addressed by Advocacy in the regulatory process and the changes made by agencies in response to recommendations and criticisms made by Advocacy of regulatory proposals. Advocacy has been assisted in its efforts by the 1996 amendments to the RFA, which we are convinced have increased agency awareness of the requirements of the law. And, although there still remain significant deficiencies in compliance, agencies are in fact trying harder to comply and seeking Advocacy's guidance earlier.

Small Business Regulatory Enforcement Fairness Act – Judicial Review
By the end of 1998, the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) had been in effect for over two years. Arguably, the most significant amendment allows a small business, appealing from an agency's final action, to seek judicial review of an agency's compliance with the RFA. Small entities have taken advantage of this change in several appeals filed in 1998, and the court decisions are summarized in this report. In addition, the Office of Advocacy filed its first a*micus curiae* brief in which it detailed an agency's failure to comply with RFA and related provisions of the Small Business Act. In that case, the court remanded the rule to the agency to address the issues raised by Advocacy.

Small Business Advocacy Review Panels
The SBREFA also mandated that the Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA) convene Small Business Advocacy Review Panels to review draft regulations, which may have a significant economic impact on small businesses. In that process, small entity representatives are consulted and asked for their input on the impact of the proposed rules on their operations. In 1998, Advocacy completed work on one and participated in eight new panels convened by EPA and one panel

convened by OSHA. Small entities have brought extremely valuable information to the regulatory deliberations of the panels. As a result, major changes have been made to the agencies' draft regulations. What is important to note is that these changes were accomplished without sacrificing the agencies' public policy objectives. Unquestionably, the SBREFA panel process has had a very salutary impact on the regulatory deliberations of these two agencies.

Outreach and Advocacy's Home Page
While small entity participation has been institutionalized in the regulatory work of EPA and OSHA, small entities also need to play a meaningful role in the activities of other regulatory bodies. Small entities need to know what policy initiatives are pending that could affect their activities and what laws exist to protect their interests. To enhance access to information on such issues and on the RFA, the Office of Advocacy increased its efforts to hold small business roundtable discussions on issues affecting a broad spectrum of industries. Advocacy also makes available to the public its publications, regulatory comments, and testimony on its Internet home page at *http://www.sba.gov/ADVO/*.

Economic Impact Analyses – Essential to the Regulatory Process
Although we continue to experience positive results from the SBREFA amendments to the RFA, agency noncompliance remains an issue for some agencies. Some noncompliance is attributable not so much to ignorance of the law but, rather, to ignorance of the importance of small business to the economy and of the anti-competitive barriers that burdensome regulations can unnecessarily erect. This ignorance poses a constant educational challenge, which can only be overcome with crucial economic impact data. The Office of Advocacy will persevere in its efforts to educate small entities and federal agencies about the Regulatory Flexibility Act and the value of economic analyses in order to ensure compliance with the objectives of this important law.

I welcome questions and reactions to this report. Please call me at (202) 205-6533.

Jere W. Glover
Chief Counsel for Advocacy
June 1999

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ABBREVIATIONS

AMS	Agricultural Marketing Service
APA	Administrative Procedure Act
APHIS	Animal and Plant Health Inspection Service
BLM	Bureau of Land Management
CALEA	Communications Assistance to Law Enforcement Act
CFR	Code of Federal Regulations
CFTC	Commodities Futures Trading Commission
CPSC	Consumer Product Safety Commission
DEA	Drug Enforcement Administration
DOC	U.S. Department of Commerce
DOD	U.S. Department of Defense
DOI	U.S. Department of the Interior
DOL	U.S. Department of Labor
DOT	U.S. Department of Transportation
EAS	Emergency Alert System
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
ESA	Employment Standards Administration
FAA	Federal Aviation Administration
FAR	Federal Acquisition Regulation
FBI	Federal Bureau of Investigation
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FERC	Federal Energy Regulatory Commission
FR	Federal Register
FRA	Federal Railroad Administration
FRFA	final regulatory flexibility analysis
FSIS	Food Safety and Inspection Service
FTC	Federal Trade Commission
GSA	General Services Administration
HCFA	Health Care Financing Administration
HHS	U.S. Department of Health and Human Services
HUD	U.S. Department of Housing and Urban Development
ILEC	incumbent local exchange carrier
IRFA	initial regulatory flexibility analysis
IRS	Internal Revenue Service
ITA	International Trade Administration
IXC	interexchange carrier
LOC	Library of Congress
MMS	Minerals Management Service
MSHA	Mine Safety and Health Administration
MTMC	Military Traffic Management Command
NAAQS	National Ambient Air Quality Standards
NASA	National Aeronautics and Space Administration

NIST	National Institute of Standards and Technology
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NPRM	notice of proposed rulemaking
OA	Office of Advocacy
OFPP	Office of Federal Procurement Policy
OIRA	Office of Information and Regulatory Affairs
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
PCS	personal communications services
PEL	permissible exposure limit
PICC	presubscriber interexchange carrier charge
PL	Public Law
POTW	publicly owned treatment works
PRA	Paperwork Reduction Act
PWBA	Pension and Welfare Benefits Administration
RFA	Regulatory Flexibility Act
SAC	standards advisory committee
SBA	U.S. Small Business Administration
SBREFA	Small Business Regulatory Enforcement Fairness Act
SEC	Securities and Exchange Commission
TRI	toxic release inventory
USDA	U.S. Department of Agriculture
USC	United States Code

EXECUTIVE SUMMARY

Introduction

By the end of calendar year 1998, the amendments made to the Regulatory Flexibility Act (RFA) by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) had been in effect for two years. The impact of the 1996 amendments is clear—small entities are increasingly seeking judicial review of agency compliance with RFA, and agencies are taking their responsibilities under the RFA, as amended, more seriously. Not surprisingly, the pre-proposal workload of the Office of Advocacy has increased significantly. Advocacy is being consulted more frequently and earlier in the regulatory process—with rewarding results.

The Role of the Office of Advocacy

By way of background, Congress created the Office of Advocacy within the U.S. Small Business Administration in 1976 to be an *independent* voice for small business in the formulation of public policy. The office was given very specific statutory mandates:

- examine and report on the role of small business in the economy;
- assess the effectiveness of existing federal subsidy and assistance programs for small business;
- measure the direct costs and other effects of government regulation on small business;
- determine the impact of the tax structure on small businesses;
- study the ability of financial markets and institutions to meet small business credit needs; and
- recommend specific measures for creating an environment in which all businesses will have the opportunity to compete effectively.

The RFA imposed the additional duty of monitoring and reporting on agency compliance with the RFA.

Advocacy Functions

The work of the office is organized around these mandates. The office:

- conducts research on small business trends in the economy;
- finances independent analyses of the impact of regulations on small business;
- oversees and critiques regulatory proposals;
- forms partnerships with small business trade associations and leaders throughout the country;
- elicits input from various industry representatives on specific regulatory proposals; and
- ensures small business participation in the development of public policy.

Regulatory Issues – A More Complex Landscape
Over the years, the core functions of the office have not changed and remain designed to respond to regulatory initiatives of other governmental bodies. What has changed, however, is the complexity of the issues confronting small business. In addition, the economy has been extremely dynamic—constantly churning—with technology changing industry structure at an extremely rapid pace, adding new dimensions to the analyses of regulatory impacts on small business. In order to fulfill its statutory mandate, the office has had to develop increased expertise in areas such as:

- industrial organization economics – the study of industry structure;
- regulatory impact analyses; and
- complex issues such as telecommunications, environment, equity markets, health and safety, among others.

Data Sources – Small Business Input
The Office of Advocacy contracts with independent entities for research on specific public policy issues and maintains a data base, unique in the federal government, on small business characteristics and trends. It is also developing the capability to track the development of an individual small company over time, through its various stages of growth.

Advocacy also holds industry roundtables to provide up-to-date information on public policy, research, economic analyses, and regulatory proposals. Internet technology is further helping the Office reach out to small entities on a national basis, working with our regional advocates, to expand small business participation in the regulatory process.

The RFA Today – Impact of SBREFA

The major objectives of the 1996 SBREFA amendments were to ensure: 1) small business input in the earliest stages of the regulatory process, 2) objective agency analyses of the economic impacts of regulatory proposals on small business, and 3) increased agency compliance with the law. Small business input and economic impact analyses are crucial to rational rulemaking. They are also crucial to substantive—as opposed to merely procedural—agency compliance with the RFA.

Advocacy has found, however, that the largest hurdle to overcome is agency resistance to the concept that regulatory alternatives that are less burdensome on small business may, in fact, be equally effective in achieving public policy objectives. Economic data thus become the *force majeure* in overcoming this resistance.

Small Business Advocacy Review Panels – Their Impact and the Role of Data
The 1996 SBREFA amendments mandated that Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA) convene Small Business Advocacy Review Panels whenever these agencies determine that a regulatory proposal may impose significant economic burdens on a substantial number of small entities. The panels are convened prior to publication of a proposal for public comment. Independent data on the impact of regulatory proposals have played an important role in the deliberations of the panels—as has the input from small entity representatives. It is fair to conclude that the panel process has had a

salutary effect on the work of these two agencies and that the time spent has been productive in demonstrating that, in fact, less burdensome regulations can be equally effective in achieving public policy objectives.

Although work on the panels has been productive, it has also been time consuming. We estimate that Advocacy alone spends an average of 400 to 500 hours on each panel—for a total, in calendar year 1998, of approximately 4,500 professional hours of effort for the nine panels convened by OSHA and EPA. (This estimate does not include the time of Advocacy's contractor, nor the time of agency staff, nor the staff of the Office of Information and Regulatory Affairs of the Office of Management and Budget).

Judicial Review – Increased Agency Compliance
It became increasingly apparent in 1998 that agencies were taking the law more seriously. Several factors contributed to this turn of events, one of which is the SBREFA amendment to the RFA that allows the courts to review agency compliance with the RFA in appeals from final agency actions. Small entities have initiated several court challenges and a body of legal precedents is developing under the RFA. Advocacy's comments that critique proposals and agency noncompliance with the RFA are a matter of public record and can be used—and have in fact been cited—in appeals. As a consequence, the Office of Advocacy's comments on regulatory proposals are having greater impact, and agencies are taking them more seriously. In addition, the Chief Counsel's first *amicus curiae* brief, filed in a case in January 1998, has unquestionably increased agency awareness of the risks in failing to comply with the RFA. The brief raised issues on which the court relied to remand the challenged rule to the agency for reconsideration. Finally, we assume that agencies are watching court decisions on RFA with a view to avoiding RFA challenges to their regulations.

Increased Pre-Proposal Activity
Further evidence that agencies are taking the RFA more seriously is the increased time spent by Advocacy in discussions with agencies *prior to* publication of regulatory proposals. Advocacy is having an impact in these early regulatory deliberations but the impacts are neither measurable nor reportable since such discussions are often not a matter of public record. Such efforts are nevertheless important and undoubtedly are the direct result of the 1996 statutory amendments to the RFA and Advocacy's increased expertise in economic analyses and arcane technical issues. If the Office of Advocacy can influence the form and content of rules before they are published for public comment, then Advocacy is doing its job more effectively. Changes are easier to effect *prior to* rather than *after* publication of a proposal. Nevertheless, Advocacy's comments for the record on regulatory proposals are still important and are summarized in this year's report. The Office Advocacy targets its efforts to rules with major impacts on small business—on which Advocacy can make a difference—and on rules where small business was underrepresented in the rulemaking process.

Advocacy Activities – Calendar Year 1998

In brief, Advocacy's formal regulatory activities included:

- participation in eight new EPA SBREFA Advocacy Review Panels, one new OSHA panel, and completion of work on one other EPA panel;
- submission of 69 formal comments for the public record on other regulatory proposals;
- review of 1,600 rules; and
- development of specific economic impact analyses and guidance to agencies in 15 instances.

Conclusion – Regulatory Savings

The true measure of the impact of the RFA and Advocacy's activities is the regulatory savings that result from changes made to regulations to reduce the burden on small business while still achieving public policy objectives. Estimating savings is an imprecise art and savings attributable to some regulatory changes cannot be estimated at all. Given these caveats, in calendar year 1998, Advocacy nevertheless estimates that changes made to regulatory proposals saved small business $1.5 billion in regulatory costs. This underscores the importance of the RFA to rational rulemaking and to the underlying premise of the RFA—namely, that regulations need not sacrifice public policy objectives by accommodating the economic landscape or by avoiding regulatory barriers to competition.

The *Annual Report of the Chief Counsel for Advocacy on Implementation of the Regulatory Flexibility Act, Calendar year 1998* contains the following chapters:

- The Regulatory Flexibility Act – An Overview;
- RFA Litigation in 1998; and
- Highlights of RFA Regulatory Activities in 1998

The report also includes the Office of Advocacy's 1998 regulatory comments (Appendix A), the office's specific economic analyses and guidance given to agencies (Appendix B), testimony of the Chief Counsel for Advocacy on SBREFA (Appendix C), and the complete text of the RFA, as amended by SBREFA (Appendix D).

THE REGULATORY FLEXIBILITY ACT – AN OVERVIEW

The Regulatory Flexibility Act (RFA) requires each federal agency to review its regulatory proposals to determine if a new rule will have a significant impact on a substantial number of small businesses and other small entities. The law also requires agencies to identify regulatory alternatives that may minimize the economic impact, such as paperwork burdens, capital investment, costs related to compliance, etc.[1] The major goals of the act are to ensure that federal agencies analyze the impact of regulations on small business and competition, communicate and explain their findings to the public, and provide appropriate regulatory relief to small entities without sacrificing related public policy objectives.

The Regulatory Flexibility Act was enacted in 1980 and amended by the Small Business Regulatory Enforcement Fairness Act of 1996.[2]

In enacting these laws, Congress made several findings, namely that regulations often:

- adversely affect competition, discourage innovation, and restrict improvements in productivity;
- create entry barriers in many industries and discourage entrepreneurs from introducing beneficial products and processes;
- apply the same provisions to small entities even though they may not be the major cause of the problem being addressed by government action; and
- impose unnecessary burdens on the small entities.

Research performed by the Office of Advocacy and others has repeatedly demonstrated the validity of these findings and substantiated the contributions small businesses make to the economy. Specifically, small businesses create most of the new jobs, hire a more diverse work force, account for the bulk of U.S. gross domestic product, and contribute most new commercial innovations. The dominant players in today's economy are not the Fortune 500 companies; rather, they are the emerging and fast growing small businesses.

Yet, independent research funded by the Office of Advocacy has also documented that small firms are disproportionately burdened by the cost of regulations. Firms with 20 to 49 employees reported spending nearly 20 cents of every revenue dollar to pay for the paperwork and compliance costs attributable to regulations. The very smallest firms, those with one to four employees, spend annually as much as $32,000 per employee on regulatory compliance. These burdens do not include the cost of initial capital investments required for compliance.[3] In fact,

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[1] Section 601 of the Regulatory Flexibility Act defines "small entities" as small businesses, small organizations, and small governmental jurisdictions; therefore most of the references in this report apply equally to small organizations and small governments. The definition of small business for each standard industrial classification is located at 13 CFR Part 121.

[2] P.L. 104-121. For full text of the code, see Appendix D.

[3] Thomas D. Hopkins, *A Survey of Regulatory Burdens*, report no. PB95-263190, prepared by Diversified Research, Inc., for the U.S. Small Business Administration, Office of Advocacy (Springfield, Va.: National Technical Information Service, 1995).

the burden of compliance is as much as 50 percent more for small businesses than for their larger counterparts.[4]

Recognizing that small business is a major source of competition and economic growth, Congress enacted the RFA to establish an analytical process that federal agencies are to follow in designing regulations that achieve statutory and regulatory goals without harming or imposing undue burdens on small businesses. The RFA does not seek preferential treatment for small businesses. Nor does it mandate that agencies adopt regulations that impose the least burden on small entities, nor require exemptions for small entities. Rather, it establishes an analytical process for determining how public policy issues can best be addressed without erecting barriers to competition. The law seeks a level playing field for small business, not an unfair advantage. It calls for regulations that are "right-sized" — that is, regulations that require small business compliance only to the extent to which small businesses contribute to the problems that a given regulation is designed to eliminate or control. To this end, agencies must analyze the impact of proposed regulations on different-sized entities in various industry sectors. The comparative effectiveness of regulatory alternatives in resolving public policy concerns while minimizing adverse impacts on competition and undue burdens on small businesses.

In 1996, the Small Business Regulatory Enforcement Fairness Act (SBREFA) amended the RFA to:

- allow aggrieved small businesses, appealing from agency final actions, to seek judicial review of agency compliance with the RFA;
- reaffirm the authority of the Chief Counsel for Advocacy to file *amicus curiae* (friend of the court) briefs in regulatory appeals brought by small entities;
- expand the application of the RFA to interpretive rules of the Internal Revenue Service that impose a collection of information requirement; and
- mandate a process for small business participation in the development of rules by the Environmental Protection Agency and the Occupational Safety and Health Administration.

Components of the Regulatory Flexibility Act

Federal agencies must comply with several basic requirements of the RFA. The Environmental Protection Agency and Occupational Safety and Health Administration are subject to special mandates that require them to consult small businesses in the development of regulations. In addition to regulatory analyses, agencies must publish a semi-annual agenda of planned regulatory activities and review existing rules periodically. Under the RFA, an agency's compliance is subject to judicial review, and the Chief Counsel for Advocacy retains the authority to file *amicus curiae* briefs in appeals from final agency actions brought by small entities.

[4] U.S. Small Business Administration, Office of Advocacy, *The Changing Burden of Regulation, Paperwork, and Tax Compliance on Small Business: A Report to Congress*, report no. PB96-113642 (Springfield, VA.: National Technical Information Service, 1996).

Agency Compliance Requirements

Economic Impact Analysis or Certification of New Rules
Federal agencies are required by the RFA either to certify that "the rule will not have a significant economic impact on a substantial number of small entities," and provide a factual basis for the determination, or prepare a regulatory flexibility analysis.

Initial Regulatory Flexibility Analysis
If a proposed rule is expected to have a significant economic impact on a substantial number of small entities, an initial regulatory flexibility analysis (IRFA) must be prepared and published in the *Federal Register* for public comment. If the analysis is lengthy, the agency may publish a summary and make the analysis available upon request. This initial analysis must describe the impact of the proposed rule on small entities. The initial analysis must also contain a comparative analysis of alternatives to the proposed rule that would minimize the impact on small entities and document their comparative effectiveness in achieving the regulatory purpose.

Certification
If a regulation is found not to have a significant economic impact on a substantial number of small entities, the head of an agency may certify to that effect, but must provide a factual basis for this determination. This certification must be published with the proposed rule in the *Federal Register* and is subject to public comment in order to ensure that the certification is warranted.

Final Regulatory Flexibility Analysis
When an agency issues a final rule, it must prepare a final regulatory flexibility analysis (FRFA) or certify that the rule will not have a significant impact on a substantial number of small entities and provide a statement of the factual basis for such certification. The final regulatory flexibility analysis must:

- provide a succinct statement of the need for, and objectives of, the rule;
- summarize the issues raised by public comments on the IRFA (or certification) and the agency's assessment of those issues;
- describe and estimate the number of small entities to which the rule will apply or explain why no such estimate is available;
- describe the compliance requirements of the rule, estimate the classes of entities subject to them and the type of professional skills essential to compliance;
- describe the steps followed by the agency to minimize the economic impact on small entities consistent with the stated objectives of the applicable statutes; and
- give the factual, policy, and legal reasons for selecting the alternative(s) adopted in the final rule, explaining why other alternatives were rejected.

The FRFA may be summarized for publication with the final rule; however, the full text of the analysis must be available for review by the public.

Requirements for OSHA and EPA

The 1996 SBREFA amendments require the Environmental Protection Agency and the Occupational Safety and Health Administration to take extra steps to include small businesses in the development of regulations. If either agency is preparing an initial regulatory flexibility analysis, it must first seek input from representatives of small entities prior to publication of the proposed rule. A Small Business Advocacy Review Panel, consisting of representatives from the rulemaking agency, the Chief Counsel for Advocacy, and the Administrator of the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB), is to be convened. The panel is to review any materials prepared in connection with a rule under consideration and to solicit small businesses' input on the proposal. The panel has 60 days in which to submit a report on its findings. This report becomes part of the public rulemaking record. The agency may reconsider the draft proposal and its economic analysis after receipt of the panel's report. The Chief Counsel for Advocacy may grant a waiver of the panel requirement under certain circumstances.

Semi-Annual Agendas

In April and October of each year, federal agencies are required to publish a regulatory agenda listing all rules expected to be published in the *Federal Register* during the coming year that will likely have a significant economic impact on a substantial number of small entities. Publication of these agendas is intended to increase the amount of time small entities will have to react to agency proposals.

Periodic Review

Federal agencies must review regulations within 10 years of promulgation to reassess their impact on small entities and make a determination whether a rule should be revised or eliminated.

Judicial Review

The Small Business Regulatory Enforcement Fairness Act amended the RFA to permit judicial review of agency compliance with the law. Adversely affected or aggrieved small entities, appealing from an agency's final action, may also seek review of an agency's compliance with the RFA. Judicial review also applies to appeals from interpretative rules issued by the Internal Revenue Service that impose information collection requirements on small entities.

Amicus Curiae Authority

Congress reaffirmed the authority of the Chief Counsel for Advocacy to file *amicus curiae* briefs in appeals brought by small entities from agency final actions. The Chief Counsel is authorized to present views on an agency's compliance with the RFA, the adequacy of the rulemaking record with respect to small entities, and the effects of the rule on small entities.

RFA LITIGATION IN 1998

Small entities are increasingly challenging agency final actions and seeking review of agency compliance with the RFA. Cases have been filed against the Federal Aviation Administration, the Environmental Protection Agency, the Health Care Financing Administration, the Bureau of Land Management, the National Marine Fisheries Services, the Federal Communications Commission, and the Mine Safety and Health Administration. Furthermore, the Office of Advocacy filed its first *amicus curiae* brief in January, 1998.

Throughout 1998, precedents have been established by the courts under the judicial review provisions of the RFA.[5] The courts have reviewed issues ranging from the adequacy of the RFA analysis to the appropriate definition of small entities for a particular proposal.

Appellate Court Cases

Grand Canyon Air Tour Coalition v. FAA[6]

This case involved a review of the Federal Aviation Administration's (FAA) rule to restrict access to the Grand Canyon National Park by small aircraft tour operators. The FAA rule limited tour operators' access to certain areas, the time for flying, and the frequency of flights. The FAA published the final rule on December 31, 1996—"Special Flight Rules in the Vicinity of Grand Canyon National Park"[7]—and certified that the rule would not have a significant economic impact on a substantial number of small entities.

The Office of Advocacy filed comments on the Notice of Proposed Rulemaking (NPRM), and filed a "Notice of Intent to File an A*micus Curiae* Brief," (friend of the court brief) pursuant to its authority under Section 612(b) of the RFA, to address FAA's noncompliance with the RFA. The Office of Advocacy withdrew its notice of intent in exchange for an agreement with the U. S. Department of Transportation, in which the Department agreed that the FAA would:

> "submit to the court a statement detailing the new data regarding the number of aircraft subject to the regulation,. . . [and] include in their communication to the court a statement that the agency erroneously certified under the Regulatory Flexibility Act that the final rule would not have a significant economic impact on a substantial number of small entities . . . ."

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[5] The Office of Advocacy attempts to maintain a complete record of cases and decisions that raise RFA issues. There is no provision in the RFA that requires notification of case filings be sent to the Chief Counsel. The Office of Advocacy must, therefore, depend on industry contacts for information about filings. Although the Office of Advocacy has written to the Department of Justice in October 1998, and again in March of 1999, requesting that the Department of Justice provide information on such filings, to date Justice has not provided the requested information.

[6] 332 U.S. Ct. App. D.C. 133 (1998).

[7] 61 Fed. Reg. 69,302 (1996).

The court found that the FAA performed a lengthy analysis. It also found that the FAA satisfied the requirements necessary to demonstrate a rational decision-making process that it responded to relevant comments, and considered reasonable alternatives.[8]

Motor & Equipment Manufacturers Ass'n v. Nichols[9]

The appellants challenged the EPA's decision to permit California to enforce its own regulations of the on board emissions devices (OBDs) pursuant to Section 209(b) of the Clean Air Act (the "waiver decision") and the EPA's rule deeming compliance with the California diagnostic device regulations to constitute compliance with the federal diagnostic device regulations (the "deemed-to-comply" rule). The appellants also argued that the EPA failed to comply with the RFA.

Appellants/plaintiffs represented businesses that manufacture, rebuild, and sell car parts in the automobile "aftermarket." Appellee/defendant Nichols was the assistant administrator for EPA. The suit also named Carol Browner, administrator for the EPA, and the EPA as defendants.

In ruling that California OBD rules were sufficient to constitute federal compliance, the EPA concluded that the rule would not have a significant economic effect on a substantial number of small businesses and, therefore, did not conduct a regulatory flexibility analysis on those entities. In making its determination, the EPA only considered the impact on large and small volume automobile manufacturers, which did not include the businesses that the plaintiffs represented. The plaintiffs asserted that the impact on automobile aftermarket should have been considered as well.

The court found that the RFA does not contemplate an analysis in such situations.[10] The court stated:

> "While EPA only considered whether its deemed-to- comply rule would have 'a substantial impact' on 'large and small volume automobile manufacturers,' . . . , it was not obliged to conduct a regulatory flexibility analysis for any other business, including the businesses represented by petitioners. An agency is under 'no obligation to conduct a small entity impact analysis of effects on entities which it does not regulate.' *United Distribution Cos. v. FERC*, 88 F.3d 1105, 1170(D.C. Cir. 1996); *see also Mid-Tex Elec. Co-op, Inc. v. FERC*, 773 F.2d 327, 342 (D.C. Cir. 1985). Because the deemed-to-comply rule did not subject any aftermarket businesses to regulation, EPA was not required to conduct a flexibility analysis as to small aftermarket businesses. It was only obliged to consider the impact of the rule on small automobile manufacturers subject to the rule, and it met that obligation."[11]

[8] 332 U.S. Ct. App. D.C. at 154.
[9] 142 F. 3d 449 (D.C. Cir., 1998).
[10] *See* 5 U.S.C. § 605(b).
[11] 142 F. 3d at 467.

District Court Cases

Greater Dallas Home Care Alliance, Metro Home Health, Inc. v. U.S[12]

The plaintiffs sought a preliminary injunction alleging that Congress had acted irrationally and unconstitutionally in adopting legislation in 1997 changing the method of payment and reimbursement to home health care providers. The plaintiffs further alleged that the Health Care Financing Administration (HCFA) failed to abide by the RFA in implementing the legislation. Specifically, the plaintiffs asserted that HCFA violated Section 604(a)(5) of the RFA, because it did not assess the costs and benefits of available regulatory alternatives and select approaches to maximize these net benefits, including more cost effective options for regulatory relief for small businesses.[13]

The court ruled that HCFA had acted correctly and denied the plaintiffs' request for preliminary injunction. With regard to the RFA, the court stated that the underlying statute set forth in detail the formula for the new cost limits. The court stated:

> "If uniform requirements are mandated by statute, as in the [Interim Payment System] . . . , a statement to that effect by the implementing agency, i.e., HCFA, obviates the need to solicit or consider proposals which include differing compliance standards. Since the January 2, 1998, and March 31, 1998, regulations were merely the implementation of the Congressional mandate embodied in the IPS, HCFA made the appropriate statements in its regulations. See 63 Fed. Reg. 15, 717 (1998)(' . . . the statute does not allow for any exceptions to the aggregate per beneficiary limitation based on the size of the entity. Therefore, we are unable to provide any regulatory relief for small entities.')." [14]

Accordingly, the court found that HCFA was merely implementing Congress's directives and was, therefore, not required to conduct a regulatory flexibility analysis.

North Carolina Fisheries v. Daley[15] (on remand)

This case involved the Department of Commerce's National Marine Fisheries Service (NMFS). The NMFS adopted a quota for the flounder fishery. The NMFS did not perform a regulatory flexibility analysis. Instead, NMFS certified that the rule would not

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[12] In *Greater Dallas Home Care Alliance, Metro Home Health, Inc. v. United States*, 107 F. Supp. 2d 63 (N.D. Tex. 1998), the plaintiff sought to include a letter written by the Office of Advocacy, dated June 15, 1998, through a motion to reopen for additional evidence. Advocacy's letter criticized HCFA's procedure in promulgating the regulations. The Court denied the motion, stating that the letter is a legal opinion on issues fully presented and argued during the June 10-12, 1998, hearing. The court found that even if the letter contained factual information it was cumulative and duplicative of evidence presented by witnesses. The court also stated even if the letter were admissible, admitting it into evidence would be prejudicial and disruptive because the defendants would be allowed to cross examine the authors of the letter and call witnesses opposition.

[13] *Id*. at 643.

[14] *Id.*

[15] 27 F. Supp. 2d 650 (E.D. Va. 1998).

have a significant impact on a substantial number of small businesses, because the quota remained the same from 1996 to 1997. There was no indication that the NMFS did any comparison of the conditions in 1996 and 1997.

The United States District Court for the Eastern District of Virginia remanded the quota to the Department of Commerce[16] after finding that the department violated the RFA and failed to provide an economic analysis sufficient to comply with National Standard 8 of the Magnuson-Stevens Act.[17] The court ruled that the department failed to provide a proper factual statement to support its certification that maintaining the quota in the flounder fishery would not have a significant economic effect on a substantial number of small entities.

To address the department's noncompliance, the court ordered the Department of Commerce to "undertake enough analysis to determine whether the quota had a significant economic impact on the North Carolina Fishery."[18] On remand, the issue before the court was whether the secretary of commerce had discharged his responsibilities under the RFA and under National Standard 8 of the Magnuson Act to perform an economic analysis. The court granted the plaintiffs' renewed motion for summary judgment, and denied the defendant's renewed motion for summary judgment. In doing so, the court stated:

> "After review of the Secretary's so-called Economic Analysis and the independent expert's comments, the Court finds that the Secretary of Commerce acted arbitrarily and capriciously in failing to give any meaningful consideration to the economic impact of the 1997 quota regulations on North Carolina fishing communities. Instead, the Secretary has produced a so-called economic report that obviously is designed to justify a prior determination."[19]

The plaintiffs also moved for the secretary of commerce to be held in contempt of the court's October 10, 1997 order that the secretary fix each year's fishing quota including adjustments, within a reasonable period of time. The court found that the secretary of commerce failed to submit an economic analysis demonstrating the economic impacts of his quota regulations on small entities and on the sustained participation of North Carolina's fishing communities. Moreover, the court determined that the administrative record in the matter clearly revealed that the secretary utterly failed to make quota adjustments based on 1997 overages within a reasonable time period. In both respects, the secretary and the agency neglected to follow the order of the court and were in violation of the Magnuson Act and the RFA. Because the secretary and the agency did not uphold their responsibilities to the court and to Congress, the court set aside the 1997 summer flounder quota and imposed a penalty against the NMFS.

[16] 16 F. Supp. 2d 647 (E.D. Va. 1997).
[17] 16 U.S.C. § 1851 (a)(8).
[18] 16 F. Supp. at 647.
[19] 27 F. Supp. 2d 650, 668 (1998).

Northwest Mining Association v. Babbitt [20]

The Bureau of Land Management (BLM) published a final rule on February 28, 1997 that would impose a bonding requirement on hardrock mining. The rule was originally proposed in 1991. While the original proposal would have set a limit on bonding requirements, the final rule contained provisions not included in the original proposals—provisions that the public, therefore, had no opportunity to comment on. The BLM certified that the rule would not have a significant economic impact on a substantial number of small entities. However, the agency failed to substantiate its conclusions and used a series of contradictory terms to define small business.

On January 7, 1998, the Chief Counsel for Advocacy filed as *amicus curiae* (friend of the court). Advocacy challenged the agency's use of a small business size standard that was not in compliance with the Small Business Administration (SBA) standards published on compliance with the Small Business Act.[21] The brief also raised concerns about the agency's failure to comply with the Administrative Procedure Act[22] and the substance of the economic analysis put on the record by the BLM.

On May 13, 1998, the court held that:

1) the association had standing to challenge the final rule under the RFA;
2) the final rule's certification violated the RFA by failing to incorporate the correct definition of "small entity"; and
3) a remand for further proceedings was the appropriate remedy.

In finding that remand was the appropriate remedy, the court stated:

> "While recognizing the public interest in preserving the environment, the Court also recognizes the public interest in preserving the right of parties which are affected by government regulation to be adequately informed when their interests are at stake and participate in the regulatory process as directed by Congress." [23]

Southern Offshore Fishing Ass'n v. Daley[24]

The appellants questioned the NMFS's decision to reduce the quota for the shark fishery by 50 percent. They alleged that NMFS failed to comply with the requirements of the RFA by failing to prepare an IRFA, solicit comments on the IRFA, prepare a FRFA incorporating the public comments from the IRFA, and prepare a FRFA in compliance with Section 604 of the RFA.

[20] 5 F. Supp. 2d 9 (D.D.C. 1998).
[21] 15 U.S.C. §§ 631 *et seq*.
[22] 5 U.S.C. §§ 551 *et seq*.
[23] 5 F. Supp. 2d 9 at 14-15.
[24] 995 F. Supp. 1411 (M.D. Fla. 1998).

Initially, the Office of Advocacy filed to intervene as a*micus curiae* in this matter. Advocacy withdrew from the case after it was able to obtain an agreement from the Department of Justice that it would argue that the proper standard of review in RFA cases is "arbitrary and capricious."

On February 24, 1998, the court ruled that the secretary did not act in a manner that was arbitrary and capricious in relation to the cut in the quota.[25] However, in determining whether NMFS complied with the RFA, the court found that the secretary's certification of "no significant economic impact" and the FRFA failed to satisfy APA standards and RFA requirements. The court criticized the agency's economic analyses and failure to comply with the law. The court stated:

> "NMFS prepared a FRFA lacking procedural or rational compliance with the requirements of the RFA. Section 604 requires that any FRFA contain 'a summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues and a statement of any changes made in the proposed rule as a result of such comments.'[26]. . . NMFS could not possibly have complied with § 604 by summarizing and considering comments on an IRFA that NMFS never prepared. NMFS's refusal to recognize the economic impacts of its regulations on small business also raises serious questions about its efforts to minimize those impacts through less drastic alternatives. . . . NMFS may not have rationally considered whether and how to minimize the 1997 quotas' economic impacts because the agency fundamentally misapprehended the unraveling economic effect of its regulations on small business."[27]

The court remanded the agency's RFA determinations to the secretary with instructions to undertake a rational analysis of the economic effects and potential alternatives. The court retained jurisdiction over the case to review the economic analysis. Because of the delicate status of the Atlantic sharks, the court ruled that the public interest requires maintenance of the 1997 Atlantic shark quotas pending remand and further review of the court.

On remand, the NMFS prepared a draft analysis and published it for public comment. After reviewing the draft analysis, the Office of Advocacy concluded that the analysis did not comply with the RFA. Specifically, Advocacy found that the analysis lacked important substantive information about the economic impact of this rulemaking on small businesses. A major flaw in the analysis was that the agency did not use a consistent definition of the industry. Another major flaw was the fact that the analysis was based on gross revenues without considering the impact on profits. The agency also assumes a certain level of diversification that was not supported by information on the industry's

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[25] "Under the circumstances, the Secretary's actions (including the 50 per cent cut in commercial quotas for LCS) are not arbitrary and capricious. The quotas seem reasonable given the congressional mandate to rebuild over-fished stocks, the centerpiece of the Sustained Fisheries Act…." 995 F. Supp. At 1429.
[26] *See* 5 USC § 604 (a)(2).
[27] 995 F. Supp. at 1436.

structure. The Office of Advocacy's comment also addressed the agency's failure to: 1) present the economic information in a manner that could be understood by the public; 2) perform an economic analysis of the alternatives; and 3) address all of the concerns raised by the court.

On remand, the United States District Court for the Middle District of Florida issued an order on October 17, 1998, critiquing the insufficiency of the court ordered economic analysis of the effects of the reduction in the shark quota submitted by NMFS.[28] The court found, "the 1997 quota visited on shark fishermen a tangible and significant economic hardship."[29] It stated that relying on the 2,000 plus permit holders as the operative universe of shark fishermen, when a smaller pool was more representative of the industry, enabled NMFS to disperse arithmetically the statistical impact of the quotas on shark fishermen.

The court also found that "NMFS inadequately considered, and perhaps overlooked altogether, feasible alternatives or adjustments to the 1997 quotas that may mitigate the quotas' pecuniary injury to the directed shark fisherman."[30] In doing so, the court stated that "the defendant affords minimal treatment to more realistic and constructive alternatives…."[31]

To assist the court in reviewing the issue of NMFS's consideration of alternatives, the court appointed a special master for the purpose of analyzing the bona fides of the defendant's remand submission with respect to the availability of workable alternatives, regulatory and otherwise, to the 1997 shark quota. The parties had until October 21, 1998 to submit objections to the selection of Steven Rubin as the special master and to show cause why the defendant ought not to absorb the costs incurred in the employment of the special master.[32]

The master's decision is still pending.

Valuevision International, Inc. v. Federal Communications Commission[33]

In this case, the plaintiff challenged portions of a Federal Communications Commission (FCC) rule setting rates, terms and conditions for the carriage of "leased access" programming on cable systems. Among the issues raised, the plaintiff contended that the FCC violated Section 604 of the RFA. Although the FCC performed an IRFA, it only focused on the effect of the rule on small cable operators. The plaintiff argued that the FCC violated the RFA because it did not consider the interests of leased access programmers—most of whom were small businesses.

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[28] *Southern Offshore Fishing Assn' v. Daley*, No. 97-1134-CIV-T-23C, slip op at 4 (M.D.Fla. Oct. 17, 1998).
[29] *Id*.
[30] *Id*. at 7
[31] *Id*. at 5
[32] *Id* at 7-8.
[33] 149 F. 3d 1204 (D.C. Cir. 1998).

The FCC argued that the plaintiff was barred from raising the RFA issue because it failed to argue the point below. The FCC issued an IRFA with the proposed rule but the plaintiff did not comment on the fact that the FCC's finding granted too much attention to small cable operators and too little to small leased access programmers.

The court stated that, arguably, the fact that the FCC addressed the issue of small leased access programmers in the FRFA preserved the question of whether its discussion was sufficient. The court held, however, that the FCC fulfilled its obligations under the RFA. The court stated that the FCC's primary focus on small cable operators was understandable since that was the group that was directly affected by the new rule. It also stated that the FCC's conclusion that the revised rules would have only a "positive" effect on programmers because they lowered the maximum rates for leased access service, permitted resale, granted access to highly penetrated tiers, and required part-time rates to be pro-rated was sufficient to satisfy the obligations of the RFA.[34]

Although the language of Section 604 of the RFA is neutral as to the need to perform an analysis on positive or negative effects, the court interpreted the RFA as only applying to the *negative* impact of rules on small businesses. Specifically, the court stated that the RFA "provides that an agency shall accompany the promulgation of new rules with a 'final regulatory flexibility analysis' assessing the negative impact of the rules on small businesses."[35]

[34] *Id*. at 1204.
[35] *Id*.

HIGHLIGHTS OF ADVOCACY'S RFA REGULATORY ACTIVITIES IN 1998

This year, more than ever, the Chief Counsel for Advocacy and the Office of Advocacy staff worked extensively with agencies on rules before they were published for public comment to ensure compliance with the Regulatory Flexibility Act. In addition, the office worked closely with the Office of Information and Regulatory Affairs in connection with the Small Business Advocacy Review Panels convened by the Environmental Protection Agency and the Occupational Safety Health Administration. This latter activity, while labor intensive, has been particularly rewarding. Cultural changes are occurring in these two agencies as they confront data on small business regulatory impacts and as they deal with concerns raised by small entities during panel discussions.

In 1998, the Office of Advocacy continued to devote an increasing amount of resources to changing the way in which particular agencies analyze new rules, so that future compliance will be more consistent across regulatory offices within an agency. However, not every new regulation receives the Office of Advocacy's full attention. The office targets rules where its involvement can likely make a difference or where small business interests are significant, but underrepresented. Some agencies require more attention because of longstanding RFA compliance problems. Others have attracted more scrutiny by Advocacy because of an agency's increased regulatory activity.

What follows are highlights of the Office of Advocacy's work on specific regulatory proposals this year, as well as some discussion of progress being made at particular agencies and with the SBREFA panel process.

Department of Agriculture

The Office of Advocacy became involved in several rulemakings issued by the Department of Agriculture in 1998; however, Advocacy's impact is not yet known, because final rules have yet to be published on most of them.

Food Safety and Inspection Service (FSIS)

Label Review Appointments

On August 27, 1998, Advocacy submitted comments on a "notice of procedural change" that sought to eliminate face-to-face appointments with courier/expediter firms that regularly seek label approvals for meat, poultry, and egg products on behalf of their clients. The practice of allowing the appointments had been in existence for 26 years and the agency had already failed previously to accomplish the change in two rulemakings. The impact would be that all such expediter/courier firms would be out of business.

Advocacy criticized the agency for attempting to effect such a drastic change in policy without going through the traditional notice and comment process. Specifically, Advocacy took issue with the agency's assessment that the change was not a rule subject to notice and comment rulemaking and provided a legal explanation for distinguishing between a rule and a procedural change. FSIS has not published any further notices on this matter.

Agricultural Marketing Service (AMS)

Meat Grading Fees On February 20, 1998, Advocacy submitted comments to AMS regarding a proposed rule that would change the fees for federal meat grading and certification services. The agency certified, pursuant to the RFA, that there would be no significant economic impact on a substantial number of small entities. However, the agency failed to provide a factual basis for its certification as required by the RFA. In fact, the agency provided no information on the number of small entities likely to be affected and no information on costs.

Milk Marketing Orders AMS proposed a rule to consolidate the 31 federal milk marketing orders into 11 orders pursuant to the 1996 Farm Bill. The proposed rule also addressed new pricing and classifications for milk and milk products. In its May 19 1998 comments, Advocacy acknowledged a lack of expertise and resources in determining the impact of the consolidation of orders or the pricing formulae. Nevertheless, Advocacy commented that the agency should explain the basis for the 150,000-pound handler exemption and consider increasing the exemption amount if warranted.

Advocacy praised the agency for preparing an initial regulatory flexibility analysis—a first for the milk marketing division of AMS. Advocacy also praised AMS for its outreach efforts and for changing the proposed rule to reflect the significant comments offered by the industry.

Department of Commerce

The Office of Advocacy reviews regulations that are proposed by several regulatory offices within the Department of Commerce. However, the office that promulgates the majority of the regulations affecting small entities is the National Marine Fisheries Services (NMFS) of the National Oceanic and Atmospheric Administration (NOAA). This is the case because the majority of the businesses in the fishing industry are small. Moreover, many of the businesses are generational, passing from father to son. In some cases, regulations that adversely affect the fishing industry not only affect the business of fishing but also the communities that rely on the fishing industry.

The NMFS promulgates rules through fishery councils located in different geographical parts of the country. Some have better information collection systems in place and, therefore, submit more thorough analyses on proposed regulations.

Although NMFS's more recent economic analyses have shown some improvement, some issues still must be addressed. Particular areas of concern are the agency's failure to consider or analyze alternatives; its definition of the affected industry; its analyses of revenue without addressing impacts on profits; and the data that it publishes for public comment. The Office of Advocacy and the NMFS have agreed to work on resolving these issues in a non-adversarial manner, and some progress has been achieved.

National Marine Fisheries Services (NMFS)

Shark Fishery Quotas

On April 24, 1998, the Office of Advocacy filed comments on the NMFS's draft consideration of the economic effects and potential alternatives to the 1997 quotas on the Atlantic large coastal shark fishery. The draft analysis was prepared in response to the court order in the *Southern Offshore Fisheries Ass'n v. Daley* case.[36] The case was filed after the NMFS decreased the quota in the shark fishery by 50 percent while certifying that the decrease would not have a significant economic effect on a substantial number of small entities.

On remand, the NMFS prepared a draft analysis and published it for public comment. After reviewing the draft analysis, the Office of Advocacy concluded that the analysis did not comply with the RFA. Specifically, Advocacy found that the analysis lacked important substantive information about the economic impact of this rulemaking on small businesses. A major flaw in the analysis was that the agency did not use a consistent definition of the industry. Another major flaw was the fact that the analysis was based on gross revenues without considering the impact on profits. The agency also assumes a certain level of diversification that was not supported by information on the industry's structure. The Office of Advocacy's comment also addressed the agency's failure to: 1) present the economic information in a manner that could be understood by the public; 2) perform an economic analysis of the alternatives; and 3) address all of the concerns raised by the court.

On remand, the court agreed with the Office of Advocacy. At the request of the plaintiffs, the court assigned a special master to review the analysis and NMFS treatments of alternatives for the shark fishing industry. The matter is still pending before the special master.

[36] See page 13 of this report for an additional discussion of this case.

Lobster Harvest Quotas

On June 24, 1998, the Office of Advocacy submitted a comment letter on NMFS's proposed rulemaking on "Fisheries Off West Coast States and in the Western Pacific; Western Pacific Crustacean Fisheries; Bank Area Specific Harvest Guidelines." The proposal reduced the quota for the lobster harvest in Hawaii.

The RFA discussion in the notice of proposed rulemaking provided a description of the size of the industry; a statement on recordkeeping requirements; information on overlapping and duplicative rules; an assertion that alternatives are analyzed in the IRFA; and a conclusion to the effect that participants will incur increased costs, but the proposed action should result in long term economic benefits to the fishery. However, there was no quantitative information in the summary to provide the public with information for assessing the true nature of the impact or to elicit meaningful comments.

The Office of Advocacy concluded that NMFS had failed to provide an adequate summary of the IRFA as required by Section 603(a) of the RFA. Without an adequate summary, the *actual* IRFA would have to be read. However, the comment period was a mere 15 days. It was unlikely that, given such a short time frame, a small business could obtain the IRFA, analyze the material, and prepare meaningful comments.

After reading the actual IRFA, it was apparent that it lacked the kind of quantitative data necessary to evaluate the impact of the rule. Instead, the NMFS merely concluded that the "qualitative analysis presented above suggests that the proposed action is expected to have no net negative economic impact on those businesses that participate in the NWHI lobster fishery—rather the long-term impact is expected to be positive."

The "qualitative analysis" referred to in the above quotation consisted of vague statements about the three alternatives and a table on the qualitative impact. The table simply stated the alternatives, and rates the benefits and costs as high, moderate, and low. There was no indication of the basis for determining whether a cost or benefit was high, moderate, or low. Without providing the basis, there was no way to ascertain whether the assumptions were accurate or if the agency had simply employed an arbitrary standard.

The data provided in the IRFA led the Office of Advocacy to question the conclusion of no negative net economic impact on the businesses that participate in the lobster fishery. Advocacy also found that the reason for lack of quantitative data was unconvincing. In the IRFA, NMFS stated that "a quantitative analysis beyond inflation adjustments of previous operational parameters is not possible" because the fishery data has not been updated since a bio-economic model utilizing data from 1983-1989.

Given the small size of the industry and the limited location (the State of Hawaii), Advocacy contended that the lack of data subsequent to 1989 was inexcusable.

The NMFS provided an expanded analysis in the FRFA—with revenue and cost data—estimating the effects of the rule on small business.

National Institute of Standards and Technology (NIST)

Fastener Quality Act – Implementation Rules

On April 14, 1998, the NIST published a final rule implementing the Fastener Quality Act.[37] The final rule established certain testing criteria to determine the reliability of commercial fasteners. The rule allowed manufacturers to use quality assurance systems, defined in the rule, as an alternative to NIST's overall product testing and accreditation system for laboratories testing fasteners. Advocacy notified NIST that it continued to hear from small businesses concerned about the sweeping impact of the act and the implementing rule. Small manufacturers expressed reservations about what they believed to be an inadequate number of approved laboratories to test fasteners. They were concerned that demand would exceed laboratory capacity, and that the approved laboratories were not geographically distributed. Fastener manufacturers also critiqued the lack of information regarding applicability, interpretation, and enforcement of the regulations. With implementation scheduled to commence in July 26, 1998, Advocacy urged NIST to ensure that comprehensive compliance assistance be available to small entities.

Department of Defense
General Services Administration
and
National Aeronautics and Space Administration

Federal acquisition reform has been a major issue for Congress and regulatory agencies since 1994. The Federal Acquisition Streamlining Act of 1994 [38] and the Federal Acquisition Reform Act of 1996[39] represent major reform initiatives that are intended to reduce paperwork burdens on federal contractors, facilitate the acquisition of commercial products, enhance the use of simplified procedures for small purchases, and improve the efficiency of the laws governing the procurement of goods and services.

The purpose of the reforms is to make the government operate more like a commercial buyer and make it easier and more appealing for businesses to participate in government markets. Implementation of procurement laws is accomplished through regulations proposed and managed

[37] 15 U.S.C. §§ 5401 *et seq*.
[38] P.L. 103-355
[39] P.L. 104-106

by the Department of Defense (DOD), the General Services Administration (GSA) and the National Aeronautics and Space Administration (NASA).

As a result of major procurement reform adopted between 1994 and 1997, 1998 was a year of implementation, adjustment, and evaluation. In 1998, the true impact of the reforms finally began to filter out into the contracting community. The intent of the reforms clearly was to make the process more appealing for businesses, in general, to participate in the federal marketplace. Notwithstanding this noble intent, what is good for businesses in general is not always good for small businesses. Thus, it remains imperative for agencies to evaluate objectively the impact of the reforms and implementing rules on the small business community.

Military Traffic Management Command (MTMC)

Transportation of Household Goods

On November 12, 1997, DOD through the MTMC announced a change in procurement policy for its international and domestic freight, personal property, and travels and finance transportation programs. Subsequent to this announcement, the MTMC published separate notices for each of these areas. As part of these new changes, on June 10, 1998, the MTMC published proposed rules governing the transportation of household goods. The proposed rule changed the method used to calculate mileage distances. The Office of Advocacy challenged this rulemaking for failing to comply with the RFA. Advocacy disagreed with DOD's assertion that the RFA did not apply to these proposed rules and found that their impact assessment did not have a sufficient factual basis. Advocacy informed DOD of the need to perform an IRFA to evaluate the economic impact on truckers and other transporters of household goods as required by the RFA. The MTMC issued a final rule without taking in consideration the comments from the Office of Advocacy. Subsequent to issuing this rule, a number of small business household goods movers filed suit against the MTMC seeking to reverse this rule. [40]

National Aeronautics and Space Administration (NASA)

Certifications at NASA

On June 1, 1998, the Office of Advocacy wrote to the NASA administrator to express concern with NASA's insufficient factual basis for its certifications of no significant impact, pursuant to section 605(b) of the RFA. In several proposed rules from this agency, NASA certified that the rules would not have a significant impact on a substantial number of small entities. The purpose of this letter was to make the agency aware that NASA cannot use boilerplate certifications for all proposed rules and that RFA requires the agency to evaluate the impact of each proposed regulation on affected small entities.

[40] *American Moving and Storage Ass'n v. United States*, No. 99-0727 (D.D.C. 1999).

Department of Health and Human Services

The Office of Advocacy has focused greater effort and resources in the past year on the Health Care Financing Administration (HCFA)—the agency responsible for running the Medicare program. Advocacy's heightened attention was due, in large part, to massive Medicare reforms that were included in the Balanced Budget Act of 1997 (BBA).[41] As HCFA implemented these new reforms through a series of regulations, tens of thousands of small businesses were seriously impacted. Although many of the burdens were statutorily mandated under the BBA, the Office of Advocacy believed that HCFA failed to comply with the RFA and other laws designed to protect public participation in the rulemaking process. In recent months, HCFA has indicated a willingness to look more carefully at the RFA and its requirements. In addition, at least 100 HCFA staff participated in a RFA and regulatory analysis training session conducted by the Office of Advocacy.

With regard to the Food and Drug Administration, several (but not all) offices within the agency have made a serious new effort to work with Advocacy on a prospective basis during the preliminary stages of rulemaking. This process of keeping Advocacy informed and considering small business impacts in the earliest stages of a rule is helpful in making better, less costly regulations.

Food and Drug Administration (FDA)

Dietary Supplements Containing Ephedra

The FDA published a proposed rule that would cause dietary supplements to be considered adulterated if they contained eight milligrams or more of ephedrine alkaloids per serving, or their labeling suggested or recommended conditions of use that would result in intake of eight milligrams or more in a six-hour period or a total daily intake of 24 milligrams or more. Certain label warnings were also required. One major effect of the rule would be to eliminate completely the use of these supplements as a weight loss aid. Tens of thousands of distributors (many of whom were individual direct marketers) would be out of business.

Advocacy submitted comments to the FDA on February 3, 1998 that questioned the agency's legal authority to regulate an entire class of supplements in this fashion (rather than on a product-by-product basis); whether the agency had accounted for all types of entities affected; whether the agency had considered all significant alternatives pursuant to the RFA; whether the agency violated the Unfunded Mandates Act;[42] and whether the agency had relied on faulty/misleading scientific evidence to support the need for the regulation. The OMB held a hearing with Advocacy, the industry and FDA staff in June 1998 to discuss the issues addressed above. Subsequently, the General Accounting Office (GAO)

[41] P.L. 105-33.
[42] P.L. 104-4.

requested a meeting with Advocacy in October 1998 to discuss Advocacy's comments as part of the GAO's investigation for an upcoming report on the dietary supplement regulation. The FDA is awaiting the outcome of GAO's report prior to finalizing the regulation. In any event, Advocacy's comments helped call attention to the need for a thorough investigation into the regulation.

Labeling Fresh Unpasteurized Juices

Because Advocacy had written numerous comments to the FDA in the previous 12 months, the FDA took the initiative to advise Advocacy of an upcoming proposed rule that would require manufacturers of fresh juices to place warning labels on their products. The FDA outlined the steps it took to minimize the burden on small entities like allowing flexibility in the type of label used. Specifically, the FDA allowed regulated entities to use inexpensive signs or placards prior to permanently placing the warning on packages or until they could initiate a new hazard analysis and critical control points (HACCP) program—the subject of a separate regulation. Advocacy drafted a letter to the FDA on June 10, 1998 expressing appreciation for the agency's initiative in consulting with Advocacy, and recommended that 1) only reasonable enforcement actions should be taken for good faith violations, and 2) the comment period be extended for everyone (and not just the handful of individuals who requested the extension). The extension was granted.

Labeling Rubber-Containing Medical Devices

This regulation was also mentioned in Advocacy's 1997 Annual Report of the Chief Counsel. In the 1997 report, it was noted that Advocacy commented about the insufficient data and analysis concerning the impact of this rule that would require warning labels for rubber-containing medical devices. The agency had initially certified that the rule would not have a significant economic impact on a substantial number of small entities (pursuant to the RFA), but provided no information on cost. The final rule mentioned a potential $2,000 per-firm cost, but FDA provided no basis for the estimate. Subsequent to Advocacy's 1997 RFA report, the agency published a new final rule with an amended economic analysis on June 1, 1998. The agency cited Advocacy's comments as the reason for the change. The agency still certified the rule, but provided some analysis to support its conclusions. The agency also added a provision allowing businesses to use temporary stickers until permanent labels could be printed. On August 31, 1998, the FDA published a new impact analysis addressing industry comments submitted in response to the June amendments. The new analysis announced a stay of the effective date for an additional 270 days for certain types of packaging.

Dietary Supplement Advertising/Disease Claims

The FDA published a proposed rule outlining definitions of the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the human body. The proposed rule also establishes criteria for determining when a statement about a dietary supplement is a prohibited disease claim. Advocacy commented informally to the OMB during the pre-proposed rule stage in March 1998, and the FDA consulted with Advocacy in April 1998 regarding its use of a non-SBA size standard in defining "small business" for the dietary supplement industry.

Advocacy's October 14, 1998 comments dealt with expanding the definition of "disease" and the impact that such a change would have on the industry. Expanding the definition to include otherwise legal, truthful and non-misleading statements about the effects of a product on the normal structure or function of the body could have a severe economic impact on the small entities who manufacture and market the supplements. Advocacy recommended listing specific examples of claims that comply with the current definition of disease to reduce consumer and industry confusion.

Since Advocacy commented on the proposed rule the House Committee on Government Reform has held a hearing on March 25, 1999 to flesh out some of the problems with the regulation. At that hearing, the FDA's commissioner acknowledged that the definition of disease needed to be resolved.

Health Care Financing Administration (HCFA)

Outcome and Assessment Information System (OASIS)

Pursuant to the BBA, HCFA published OASIS regulations in 1998 that would require home health agencies to conduct a specific, comprehensive assessment for each patient to determine the patient's immediate care and support needs. Under the proposed regulations, home health agencies would be required to use lengthy standardized forms when evaluating patients at the beginning and end of care, and every 60 days between the beginning and end of care. The data would eventually be used to calculate a prospective payment system for home health agencies. The OMB requested Advocacy comments on the impact of the OASIS final rule prior to its publication. On December 23, 1998 Advocacy submitted comments to OMB recommending: 1) OASIS be required for Medicare patients only (as opposed to all patients); 2) only relevant core data should be collected; 3) the 19-page reassessment forms be shortened/condensed when there has been no change in the patients care or condition; and 4) HCFA should be conservative in its enforcement on small home health agencies that are attempting to comply. The HCFA only agreed to include in the final rule a request for comments on how to shorten the reassessments. Under

pressure from the White House and Congress and amid concerns about the reassessment questions and the privacy issues they raised, the HCFA reconsidered its policy on collecting the information from non-Medicare patients and announced that the data collection would still be required, but home health agencies would not have to give it to the HCFA on the April 26, 1999 effective date. Finally, the HCFA announced on April 7, 1999, that it was delaying until further notice the effective date for the OASIS regulations.

Competitive Bidding for Durable Medical Equipment

The BBA permits the HCFA to implement up to five demonstration projects under which competitive acquisition areas are established for contract award purposes for the furnishing of certain services and/or items. The first demonstration project announced by the HCFA is located in a Florida county and seeks to limit the number of providers in the designated area for five types of durable medical equipment and home medical equipment supplies. Advocacy submitted comments to the HCFA on November 2, 1998 (and a correction notice on January 27, 1999) expressing concern about the potential impact on small suppliers in the demonstration area because of their inability to compete with larger companies for low prices. Because of Advocacy's concern, the OMB held several meetings with interested trade associations, the HCFA and Advocacy to address small business concerns relating to the bidding requirements. Advocacy subsequently submitted comments to the OMB on December 18, 1998, and several changes were eventually made to the bidding forms and procedures to make it easier for small businesses to compete.

Medicare Reimbursement Schedule for Portable Providers

Portable x-ray providers are technologists who transport x-rays and EKGs to sick and elderly patients—most of whom reside in nursing homes. Under authority of the BBA, the HCFA issued a proposed rule changing the methodology for establishing fees for physicians and for portable x-ray set-up and transportation based on average allowable charge data. According to anecdotal evidence, the new fees amounted to a 45 percent overall reduction for providers. On September 10, 1998, Advocacy submitted comments to the HCFA indicating that it may not have complied with the RFA because its regulatory analysis lacked several of the elements required for an IRFA. On November 18, 1998, Advocacy submitted comments on the final rule as well, because the agency failed to respond specifically to the concerns raised by Advocacy and the industry during the comment period in violation of the RFA. The HCFA did correct two technical errors in the proposed and final rules that resulted in a reduced burden. However, in an April 2, 1999 letter to Advocacy, the Administrator of the HCFA maintained that the industry's concerns and comments were not unique and that the agency responded to industry concerns generally in the final rule.

Home Health and Interim Payment System

On March 31, 1998, the Office of Advocacy filed a petition for reconsideration with the HCFA opposing a direct final rule that had a tremendously negative impact on the home health care industry. In an attempt to curb Medicare spending, fraud and abuse, the HCFA changed its reimbursement policy from one which was based on reasonable or actual costs to one that was based on caps/limits determined by historical costs for some agencies, but national average costs for other agencies. The HCFA's authority to promulgate this interim payment system (IPS) regulation again came from the BBA. Under IPS, agencies are reimbursed in an inequitable fashion regardless of whether the agency operated efficiently in the past and regardless of the number of high-cost medically complex patients that are typically treated by the agency. To compound the situation, the caps/limits were made retroactive to October 1997.

According to industry data, approximately 2,000 home health agency offices have closed nationally since implementation of IPS, because they either cannot afford to pay hundreds of thousands of dollars in overpayments to the HCFA, or they can no longer afford to operate. Advocacy's challenge to the rule was based on the fact that the HCFA did not publish a proposed rule (and thereby denied adequate public notice and comment), and also based on the fact that the agency violated the RFA by not adequately analyzing less costly alternatives. Many constitutional challenges were filed in courts nationally, but were unsuccessful. Based on Advocacy's efforts and a lobbying effort by the industry, Congress included some minor relief in a subsequent budget bill (e.g., some increases in per-visit and per-beneficiary cost limits, and the 15 percent across-the-board reduction in payments scheduled for 1999 was delayed until 2000). Congress has promised to revisit the issue in 1999 if the industry can unite in a solution.

Home Health and Surety Bonds

Home health surety bonds are yet another BBA initiative. Advocacy filed a petition for reconsideration with the HCFA on April 15, 1998 requesting that the HCFA implement only those portions of the regulation that were required under the BBA, and also requesting that the HCFA publish a proposed rule (rather than a direct final rule) and adequately analyze alternatives. To address fraud and abuse, and be assured that overpayments would be repaid to the agency, the HCFA proposed a final rule that would have required all home health agencies to obtain surety bonds in an amount which is the greater of $50,000 or 15 percent of the previous year's Medicare reimbursement. The regulation also required a three-month minimum capitalization requirement. Congress had only required the HCFA to establish a minimum $50,000 surety bond.

Small home health agencies could not afford the premiums for the bonds, and they certainly could not meet the collateral requirements necessary to

obtain the bonds. Moreover, the surety industry expressed concern that they were subject to potentially unlimited liability under the proposal if they supplied bonds to the industry. The HCFA did go back and clarify the regulation to limit a surety's liability, but did nothing to change the bond requirements for the home health industry.

On July 15, 1998 the Chief Counsel for Advocacy, Jere W. Glover, testified before the Senate Small Business Committee on the impact of the regulation on small business. Advocacy's petition was circulated to each member of Congress by the industry, and eventually published, in its entirety, in the *Congressional Record*. Senator Bond of the Small Business Committee introduced a resolution of disapproval (under the SBREFA) to void the regulation. After Senator Bond obtained 50 other co-sponsors, the HCFA decided to delay implementation of the regulation indefinitely until further study could be done. Since that time, GAO published a report in early 1999 confirming that small businesses can least afford the collateral requirements for a 15 percent bond and stating many of the same conclusions Advocacy had stated in its April 1998 communication to the HCFA.

Medicare Payment for Ambulance Services

The HCFA proposed this regulation to reduce Medicare costs resulting from the use of ambulances where no medical necessity exists or where reduced services may suffice. The HCFA proposed to base Medicare reimbursement on the beneficiary's medical condition rather than the type of vehicle used. The rule would have required ambulance services to document and submit to the HCFA a record of the level of medical care needed by a beneficiary based on certain limited and pre-determined codes. The rule also proposed to narrow the definition of an ambulance by requiring a certain number of personnel to operate each vehicle as well as requiring certain minimum supply and equipment levels.

Based on Advocacy's November 4, 1997 comments and comments by concerned industry representatives, the HCFA agreed (in a January 25, 1999 final rule) not to require physician certification for ambulance service in non-emergencies when the beneficiary resides at home (allowing for the presumption that a patient receiving treatment at home was under ongoing physician care). The agency also agreed to allow physician certifications 48 hours after non-emergency unscheduled service—rather than before service. Most importantly, the definition of Advanced Life Support and Basic Life Support, as well as the specific allowable fees, will now be the subject of a negotiated rulemaking comprised of interested industry representatives.

Department of Housing and Urban Development

In 1998, the Department of Housing and Urban Development (HUD) became more actively involved with the RFA. In addition to requesting informal assistance from the Office of Advocacy on a variety of draft and proposed regulations, HUD staff requested a RFA briefing for their program offices.

Mortgage Brokers At the end of 1997, the HUD issued a proposed rulemaking on the disclosure of fees paid to mortgage brokers under the Real Estate Settlement Procedures Act.[43] In 1998, the Office of Advocacy met with the staff of the HUD to discuss the certification prepared for the proposed rulemaking. In addition, the Office of Advocacy offered guidance on how to perform an IRFA for the rulemaking.

Uniform Physical Conditions Standards The Office of Advocacy held several discussions with the staff of the HUD on the impact of the proposed rulemaking for Physical Condition Standards and Physical Inspection Requirements for Certain HUD Housing on small entities and governments.

RFA Briefing At the request of the staff of the HUD, the Office of Advocacy conducted a seminar on the RFA and the SBREFA. This seminar included how the RFA applies to small entities and to small governmental jurisdictions.

Lead-Based Paint In November 1998, Advocacy submitted comments on an IRFA published with HUD's proposed rule: Requirements for Notification, Evaluation, and Reduction of Lead-Based Paint Hazards in Federally Owned Residential Property and Housing Receiving Federal Assistance. The rule delineated steps that owners and renters of housing receiving federal assistance must take to notify their tenants of lead-based paint hazards. The rule would also require owners and renters of these properties to mitigate lead-based paint hazards, up to, and including, removal of lead-based paint.

Pursuant to the RFA, the HUD published an IRFA for public comment, yet certified in the IRFA that the proposed would not have "a significant impact on a substantial number of small entities." The Office of Advocacy assessed in its comments that this rulemaking was incorrectly certified, since no factual basis was provided to explain the agency's certification.

In response to Advocacy's comments, the HUD acknowledged that there was a "significant impact," and outlined several regulatory alternatives to address small business concerns.

[43] 12 U.S.C. §§ 2601 *et seq*.

Department of Interior

The Department of Interior (DOI) has several regulatory entities charged with overseeing the country's natural resources. The regulatory issues of these agencies are varied. Some of the most important issues for small entities are oil, minerals, hardrock mining, reclamation, fish, wildlife, and parks.

Historically, the DOI's compliance with the RFA has been problematic. Prior to 1998, the DOI's regulatory flexibility analyses consisted of either a single sentence stating that the proposal would not have a significant economic impact on a substantial number of small entities or a recitation of what the RFA requires an agency to do for compliance. The statements rarely included any information on the economic impact of the proposed rule on small entities.

To address the compliance problems, the Office of Advocacy has begun working directly with regulators at the DOI. Advocacy has held seminars to discuss the importance of RFA compliance and the steps necessary for a proper economic analysis. Advocacy also invited regulators from the DOI to industry roundtable discussions on the RFA. These efforts have resulted in increased communications between the Office of Advocacy and the agencies at the DOI. In fact, in 1998 the DOI met with Advocacy on specific RFA issues and sought Advocacy's input on proposals prior to their publication in the *Federal Register*.

Although the DOI's overall performance continues to be problematic, its compliance with the RFA did show some improvement in 1998—namely, their proposals no longer contain boilerplate certifications of no significant economic impact. In general, the DOI's RFA regulatory discussions in 1998 usually had some factual basis for the public to consider. The issue still remains as to whether the agency has provided the sufficient economic data, whether it fully analyzed available information, and whether the information provided supports the conclusion reached by the agency.

The Department's increased interest in RFA compliance issues is probably due in large part to the court opinion in *Northwest Mining Association v. Babbitt*.[44] In that case, the United States District Court for the District of Columbia remanded a Bureau of Land Management bonding rule to the agency because of the agency's failure to comply with the RFA.

Bureau of Land Management (BLM)

Hardrock Mining On January 7, 1998, the Office of Advocacy filed its first *amicus curie* brief. The case, *Northwest Mining v. Babbitt*, raised issues about a trade association's standing to bring a claim under the RFA and the BLM's failure to use the proper size standard for determining the number of small businesses that may be harmed by the regulation.

[44] See page 13 of this report for an additional discussion of this case.

In May 1998, the District Court for the District of Columbia agreed with Advocacy's arguments and ruled in favor of the plaintiff. First, the court found that the RFA extends standing to trade associations to sue to small entities. Small entity as defined in the RFA includes the term "small organization" which means any not-for-profit enterprise that is independently owned and operated and is not dominant in its field. Since the plaintiff was a small not-for-profit organization, it was a small entity and, therefore, met the requirements for standing under the RFA.

In terms of the agency use of an alternate size standard, the court stated that the BLM's reasons for using another size standard were "unconvincing in light of the clearly mandated procedure of the RFA. The definitions section of the RFA uses phrases such as ''small entity' *shall have* the same meaning. . .' . . . Words such as these do not leave room for alternate interpretations by the agency."[45] It found that since the BLM's certification was without observance of procedure required by law, the Plaintiff was entitled to relief. Although the agency argued that maintenance of the rule was necessary to save the environment, the court disregarded that argument stating:

> "While recognizing the public interest in preserving the environment, the Court also recognizes the public interest in preserving the rights of parties which are affected by government regulation to be adequately informed when their interests are at stake and to participate in the regulatory process as directed by Congress."[46]

Minerals Management Service (MMS)

Postlease Operations

On April 17, 1998, the Office of Advocacy submitted comments on the MMS's proposed rule on post-lease operations. The proposal allowed the MMS to grant an easement and a right of use for an outer continental shelf tract to a state lessee. It also clarified the distinction between granting and directing a suspension, set out criteria to disqualify an operator with poor operating performance from acquiring any new lease holdings, and required written accident reports. The MMS certified that the proposal would not have a significant economic impact on a substantial number of small entities.

The Office of Advocacy commended MMS for including a factual statement with its certification. However, the Office of Advocacy questioned the absence of supporting data in the factual statement as well as the propriety of the certification. The Office of Advocacy performed a threshold analysis to provide MMS with an example of the type of factual data that should be published to support a certification under the RFA.

[45] 5 F. Supp 2d 9, 14 (D.D.C. 1998).
[46] *Id*. at 16.

Department of Labor

The Department of Labor has broad regulatory authority over wages, labor standards, and occupational safety concerns, including mine safety. One of its agencies, the Occupational Health and Safety Administration (OSHA), must observe certain requirements imposed on it by SBREFA when it is considering regulations that will have a significant impact on small entities. Advocacy has devoted significant resources to these activities in the past year.

The Pension and Welfare Benefits Administration (PWBA) proposed some major regulations at the end of 1998 and is considering others. Advocacy has consulted with the agency on size standards, held preliminary discussions on the impact of these regulations on small businesses, and filed comments.

Occupational Safety and Health Administration (OSHA)

Tuberculosis

In calendar year 1996, the OSHA convened a Small Business Advocacy Review Panel on a rule to reduce on-the-job employee exposure to tuberculosis (TB). The panel completed its work on November 12, 1996, and the OSHA published a rule on October 17, 1997. On March 5, 1998 the Office of Advocacy commented on the proposed rule on occupational exposure to TB. Many of the issues raised in Advocacy's comments were first discussed in the Small Business Advocacy Review Panel report.

TB afflicts the most vulnerable members of our society, the sick, the poor, the elderly and the homeless. In order to control worker exposure to TB, OSHA's proposal included specific workplace requirements that included, but were not limited to: the development and implementation of a written plan to control employee exposure to TB; the required use of respirators when administering certain job functions and patient care; provisions specifying the medical management of and medical recordkeeping of employees who may be exposed to TB; and detailed requirements for work practice and engineering controls. For homeless shelters alone, Advocacy concluded that the average cost would be $1000 per year and the cost for a homeless shelter with an active case of TB would be a total cost of $41,000. Similar and equally devastating economic impacts were anticipated for hospices, substance abuse treatment, and personnel service providers. Two major questions remain unanswered: What will the rule's impact on overall TB exposure risks be if entities currently servicing high risk populations have to reduce or eliminate services? Are there less costly and equally effective alternatives, including non-mandatory alternatives, that should be considered?

The Office of Advocacy encouraged OSHA to view this rulemaking as an opportunity to engage public and private health care specialists in a discussion as to the best approach for controlling this disease overall—not

just in the workplace—and what controls can reasonably be implemented in the workplace without increasing the exposure risk to the general public. Advocacy urged OSHA to address the following questions: Is OSHA's approach the best way to control this disease and protect the health of workers? Are increased requirements for costly engineering controls and patient outplacement the best allocation of very limited resources to manage TB exposure in hospices, substance abuse centers, and homeless shelters? Are such controls enforceable in these particular workplaces which are dependent on volunteer workers and charitable financial support or will there be greater compliance problems?

The OSHA continues to review the public comments before it finalizes the rule.

Steel Erection Waiver from Panel Process

In September 1997, the OSHA asked the Chief Counsel for Advocacy to waive the Small Business Advocacy Review Panel provisions of SBREFA for a rule that had been the subject of the negotiated rulemaking process. After receiving evidence of significant input into the process by small business, on January 23, 1998, the Chief Counsel, in consultation with the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, and affected small entities, granted the OSHA's request for a waiver. In granting the waiver, Advocacy nevertheless expressed concerns that the OSHA had not fully considered the impact of the rule on *all* affected small business sectors during the negotiated rulemaking process. In response, the OSHA prepared a supplemental analysis of the impact of the rule on fabricators, which was one of the industries directly affected by the rule but whose interests had not been explicitly addressed. The OSHA also published questions in the NPRM that had been developed by Advocacy, along with the supplemental impact analysis of the proposed rule, inviting small businesses to respond to the questions and the analysis.

Safety & Health Programs

On August 28, 1998, the OSHA notified the Office of Advocacy of its intention to propose a safety and health program rule that may have a significant impact on a substantial number of entities. This draft sought to reduce the number of job-related fatalities, illnesses, and injuries by requiring employers to establish a workplace safety and health program to ensure compliance with OSHA standards and the general duty clause of the Occupational Safety and Health Act.[47] The scope of the proposal was a large one, covering all employers, except those engaged in construction and agriculture.

Pursuant to Section 609(b) of the RFA, as amended by the SBREFA, a Small Business Advocacy Review Panel was convened on October 20,

[47] 29 U.S.C. §§ 651 *et seq*.

1998. The panel consisted of representatives of OSHA, the Office of Advocacy, and the OIRA of the OMB. The panel consulted with 19 small entity representatives as a part of the panel process. Those representatives voiced concerns with the draft, including: underestimated costs of compliance, vague performance language, and a need for outside expertise to assist in complying with the regulation.

At the conclusion of the 60-day panel process, a panel report was submitted to the assistant secretary for Occupational Safety and Health at the Department of Labor, indicating numerous recommendations and findings of the panel with respect to the draft rule. Some of those key findings were: 1) OSHA had underestimated the costs of the proposed rule and should review its cost estimates; 2) OSHA should clearly present information on the assumptions and estimates underlying the costs and benefits associated with the rule; 3) OSHA should more clearly identify the basis for its preliminary conclusion that state health and safety programs are effective in reducing job-related injuries and illnesses; 4) OSHA should clearly explain its draft enforcement policy; and 5) OSHA should analyze and give special attention and consideration to an alternative regulation that would regulate those industries with high risks based on reports of injuries, illnesses, and deaths—leaving other industries to be regulated under existing OSHA standards and state requirements.

Pension and Welfare Benefits Administration (PWBA)

Benefits Claims Regulations

The PWBA proposed a regulation in September 1998 that would make changes to appeals procedures for individuals who are denied benefits by their employer's health or pension plans, and the rule would also provide a tiered structure. Prior to publication, the PWBA asked Advocacy to give its views on the size standard chosen as the threshold for these provisions (i.e., plans with fewer than 100 participants). The PWBA was late in coming to Advocacy for consultation since the size determination should have been made early enough to control and direct the analysis. However, after a review of the merits of the size standard chosen, Advocacy determined that the chosen size standard was entirely appropriate since it was customarily used within the industry. Advocacy informed the PWBA that it would not object to the regulation on this basis.

Independent Audits

The Office of Advocacy organized a discussion group with key small business pension experts and the PWBA to discuss the concerns that small businesses would have if independent audits were required by regulation. The PWBA had considered requiring independent audits of plans that were not being run by accredited financial institutions. The group felt that this would place an extra burden on small businesses by raising their already high administrative costs per participant. This regulation could lead to reduced small business participation in pension plans.

Department of Transportation

The Department of Transportation (DOT) houses a number of agencies, which engage in regulations affecting various small businesses. Among those are the United States Coast Guard, Federal Highway Administration, Federal Aviation Administration, National Highway Traffic Safety Administration, Federal Transit Administration, and the Research and Special Programs Administration. The Department of Transportation as a whole has improved their analysis when determining certifications of impact upon small business, however there is still work to be done within some of the agencies. The Office of Advocacy will continue to work with the Department of Transportation in 1999 to ensure their continued compliance with the RFA.

Over-the-Road Bus Rule

In March, 1998, the DOT proposed a rule for the transportation of individuals with disabilities in an effort to implement provisions of the Americans With Disabilities Act.[48] The DOT proposed that newly purchased over-the-road buses be accessible to passengers with disabilities and required that companies (motor carriers, tour bus operators, etc.) provide accessible over-the-road-bus service. Advocacy commented that the rule as proposed would have a serious impact on the small bus industry and would cause small businesses to reduce the transportation available to the public as a whole—especially in rural areas. Advocacy suggested that a service-based alternative would provide better long- and short-term transportation to all passengers—including those with disabilities.

Advocacy convened a pivotal meeting with the DOT staff and small business representatives to discuss various issues and alternatives to the proposal which would accomplish the DOT's objective of providing bus service to the disabled, while not unduly burdening small motor carriers. The DOT agreed to review the costs projected by the small businesses. After careful study of the public docket, the DOT crafted an innovative approach, which achieved its objective while striking a balance among conflicting public policy concerns.

In September, 1998, the DOT published a final rule which transitions the private bus industry to full service for passengers with disabilities, while maintaining service for passengers who rely on small bus companies for essential needs. The Office of Advocacy complimented the DOT for its willingness to take into account important small business concerns while creating important regulations.

Industry estimates that the changes made to the proposal would save the industry about $180 million and still guarantee transportation for the disabled.

[48] 3 U.S.C. §§ 421 *et seq.*

Department of the Treasury

The Department of the Treasury performs four basic functions: 1) formulating and recommending economic, financial, tax, and fiscal policies; 2) serving as financial agent for the U.S. government; 3) enforcing the law related to these areas; and 4) manufacturing coins and currency. Of these responsibilities, formulating and recommending tax policy and enforcing tax law has the most dramatic impact on every business—large or small. Besides the Internal Revenue Service other divisions, such as the Office of Thrift Supervision, and the Bureau of Alcohol, Tobacco and Firearms, also have an impact on small business.

Under the Administrative Procedure Act (APA), interpretative rules are exempt from notice and comment rulemaking. The RFA requires analysis of a proposed regulation only where notice and comment rulemaking is required. For years the IRS has escaped the requirements of the RFA because it categorized most of the rules it promulgates as "interpretative," meaning the rules simply carry out the intent of Congress and do not impose any additional requirements. The SBREFA amended the RFA to require that interpretative rules, including those issued by the IRS, that imposed a collection of information requirement would be subject to the RFA.

Since the passage of the SBREFA amendment, the IRS has worked with the Office of Advocacy to learn more about complying with the RFA. The IRS has started either to certify rules or perform initial regulatory flexibility analyses with some consistency. In 1998, the IRS was responsive to the Office of Advocacy's questions and worked with Advocacy and other small business groups to anticipate problems and resolve them before publication of regulations.

Yet, the majority of the regulations published by the IRS in 1998 were not subject to the RFA even though SBREFA extended application of the RFA to IRS "interpretative rules" that impose a collection of information requirement. The reasons cited why the RFA did not apply to many IRS rules are as follows:

1) The RFA applies to legislative regulations. The IRS has always maintained that virtually all its regulations are interpretive and, thus, exempt from the RFA.
2) Many IRS regulations clarify definitions or provide examples of application. Without more, they do not require analysis under SBREFA.
3) Any interpretative regulation that was proposed prior to March 29, 1996 is not subject to the RFA as amended by SBREFA.
4) Most IRS regulations have an impact on individuals, large entities or activities that do not involve small businesses.
5) Even when there is a "collection of information" which the act defines to include "recordkeeping" the IRS has taken the view that only the portion of the regulation that contains such a requirement needs to be analyzed for its impact on small business.
6) The IRS has most often taken the view that unless there is a "form" required (a piece of paper that is to be filled out by the taxpayer); there is no recordkeeping requirement imposed by the rule. Also, if there is simply an addition or amendment

to an existing form, the change is insignificant, and there is no new collection of information requirement.

Internal Revenue Service (IRS)

IRS Restructuring And Reform Act of 1998

Since announcement of restructuring plans for the IRS and with the passage of the IRS Restructuring and Reform Act of 1998,[49] the IRS has undertaken a massive project to reshape the agency. The administrative changes that will evolve will have an impact on small businesses. The Office of Advocacy and small business stakeholders have been involved in a continuing process of briefings and consultations regarding these changes. The IRS has sought Advocacy's opinions on the restructure and the opinions of small business groups that Advocacy has introduced to the IRS to help analyze its future plans.

Although effort expended on this is not regulatory activity *per se*, the restructuring involves changes in the culture of the IRS that will make it more sensitive to the impact of future regulatory proposals on small business. The act itself sets out small business requirements. For example:

- The act requires the IRS to create a customer friendly attitude and a division for small business, something that Advocacy has long advocated and supported.
- The act creates an oversight board for the IRS, and a small business experienced representative is to be named to the board, as Advocacy had recommended.

Finally, the IRS, in establishing a "small business division," consulted with the Office of Advocacy to establish a size standard for the businesses that fall within the jurisdiction of the division that was suitable for serving the small businesses community.

ISO 9000

At the invitation of the IRS, the Office of Advocacy and a number of small business groups formed a working group to discuss and hopefully resolve the issue of ISO 9000. ISO 9000 is an international quality standard that U.S. manufactures must maintain in order to bid for contracts and produce products overseas. Meeting the standard requires expensive training and certifications. Small businesses would like to write these costs off on their taxes in the year the money was spent. The IRS had argued that the costs should be deducted over a period of years, to coincide with the income attributable to them. The working group proposed a clarifying revenue ruling, which the IRS is considering. This

[49] P.L. 105-206.

is an example of the IRS addressing regulatory problems directly and offering pre-proposals.

Electronic Federal Taxpaying System

The Internal Revenue Service published a requirement that businesses with employment tax obligations greater than $50,000 must pay these taxes using the electronic federal taxpaying system (EFTPS). This posed a hardship for many small businesses that were not given adequate notice of the requirement or of ways to reduce the cost of setting up the transactions. The requirement, which was a part of the implementation of the North Atlantic Free Trade Agreement, was to have gone into effect in 1997. At the insistence of the Office of Advocacy, trade associations, Congress, and other groups, the enforcement date was postponed until January 1, 1998. Advocacy renewed its concerns throughout 1998. Implementation of the EFTPS was finally postponed until the summer of 1999. Most recently, the IRS amended the requirement to minimize the hardship by raising the threshold for mandatory electronic submissions to $200,000—effectively excluding many small businesses.

Unrelated Business Income Tax

In 1997, the Office of Advocacy asked the IRS to consider a rule to clarify the application of the unrelated business income tax to travel and tour activities of nonprofit entities. Regulations were issued in April, 1998. The regulations were a collection of existing court rulings that established the boundaries of which commercial touring activities are "substantially related" to the statutory mission of a tax exempt organization. Current law requires that a commercial activity of a not for profit entity be substantially related to the purpose for which it was charted in order for the activity to be tax exempt (i.e., charitable, educational, scientific, etc.). When it became clear that a great many groups on both sides of the issue wanted to comment, Advocacy filed comments in September, 1998 requesting that the regulation be scheduled for a hearing. The IRS held a hearing at which Advocacy testified urging that a stronger standard be established to prevent tax-favored nonprofit organizations from competing unfairly against tax-paying small businesses. Advocacy argued that the RFA should apply to the regulation since it imposed a *de facto* collection-of-information requirement, meaning records would have to be kept by nonprofit organizations to establish their exempt purpose. Advocacy contended that this satisfied the law's collection-of-information standard. Finally, Advocacy pointed out that pursuing business ventures to provide financial support for other exempt activities was not a sufficient reason to circumvent the unrelated business income tax.

IRS Reg Flex Checklist

In April 1998, the IRS developed and began using a checklist for every regulation that had a small business impact. The checklist was adapted from Advocacy's guidance on how to perform a regulatory

flexibility analysis**.** The IRS also met with Advocacy's economists to review the guidance and use of the checklist.

Section 1202 - Special Small Business Stock

In February 1998, the IRS issued final regulations that amended its proposed regulation regarding §1202 Special Small Business Stock[50]— providing new redemption exemptions that had been recommended by Advocacy in comments and testimony before the IRS. These exemptions provide that certain key shareholders can leave a company and have their stock redeemed under certain circumstances without destroying the tax benefits connected to the stock. Advocacy had argued that these new redemption exemptions give the stock more flexibility and make the stock more attractive to a larger group of investors.

Simplified Forms

Advocacy continued to work with the IRS to establish one simple filing form that would satisfy the wage and tax reporting obligations of the very smallest businesses under both federal and state tax law. The single form would have the effect of "tiering" reporting requirements and would make tax reporting dramatically easier for the smallest businesses. Advocacy's research has revealed that tax reporting is a major burden and cost for small business. Therefore, Advocacy has urged the IRS to approve a simple single multi-purpose form that eliminates the duplicative information requested by federal, state, and local agencies regarding tax and wage reporting. Advocacy supported special legislation and a pilot program to help demonstrate the usefulness of "single point filing," as the program is called.

The IRS is financing a program called the state tax and wage reporting system (STAWRS). In this connection it is working with the state of Montana to manage a pilot program that will analyze the workability of a simplified multi-purpose and multi-user form with a test group of small businesses. If successful, it would be a precursor to major regulatory changes at the IRS that would reduce the reporting and paperwork burden imposed by tax regulations on small business.

Office of Thrift Supervision (OTS)

Regulatory Flexibility Analyses

In 1998, the OTS requested the Office of Advocacy's assistance on several major rulemakings. On the OTS's proposal concerning assessments and fees, the Office of Advocacy provided guidance on the IRFA and on the FRFA. In addition, OTS preformed an IRFA on the "Know Your Customer" proposed rulemaking.

[50] 26 U.S.C. § 1202.

Commodities Futures Trading Commission

In the past, the Commodities Futures Trading Commission has not published many regulations requiring compliance with the RFA. However, due to increased awareness of its obligations under the RFA, the commission has sought Advocacy's informal guidance on several occasions. This pre-proposal consultation is another example, in Advocacy's view, of the impact of the 1996 SBREFA amendments.

Consultations In 1998, the Commodities Futures Trading Commission sought the Office of Advocacy's guidance on preparation of its annual regulatory agenda and the RFA Section 610 review. In addition, the Office of Advocacy provided detailed information and guidance for several RFA certifications on proposed regulations.

Environmental Protection Agency

The Office of Advocacy continued its work with the Environmental Protection Agency (EPA) and small businesses on pre-proposed regulations in 1998. The SBREFA requires the EPA to convene Small Business Advocacy Review Panels with the Chief Counsel for Advocacy and officials from the Office of Management and Budget's Office of Information and Regulatory Affairs for proposed rules that are expected to have a significant economic impact on a substantial number of small entities. This federal panel receives recommendations from small entity representatives regarding draft proposed EPA regulations. The agency, in turn, considers the panel recommendations in the formulation of the proposed rule.

During calendar year 1998, Advocacy completed work on one and participated in eight Small Business Advocacy Review Panels convened by EPA (see table below).

In addition to its work on these panels, the Office of Advocacy worked on other issues of concern for small businesses, including Emergency Planning and Community Right-to-Know Act (EPCRA)[51] underground storage tank regulations, toxics release inventory (TRI) reporting requirements, and persistent bioaccumulative toxics chemical reporting requirements.

[51] 42 U.S.C. §§ 11011 *et seq.*

Summary of EPA RFA/SBREFA Small Business Advocacy Review Panels

Rule Title	Date Convened (scheduled)	Date Completed (scheduled)	Published NPRM
Transportation Equipment Cleaning Effluent Guideline	07/16/97	09/23/97	06/25/98
Centralized Waste Treatment Effluent Guideline	11/06/97	01/23/98	01/13/99
UIC Class V Wells	02/17/98	04/17/98	07/17/98
Ground Water	04/10/98	06/09/98	**
FIP for Regional NO Reductions	06/23/98	08/21/98	09/30/98
Section 126 Petitions	06/23/98	08/21/98	09/30/98
Radon in Drinking Water	07/09/98	09/18/98	**
Long Term 1 Enhanced Surface Water Treatment	08/21/98	10/19/98	**
Filter Backwash Recycling	08/21/98	10/19/98	**
LDV/LDT Emissions and Sulfur in Gas	08/27/98	10/26/98	**

Water Pollution Panels

Effluent Limitation Guidelines

Several Small Business Advocacy Review Panels involved effluent limitations guidelines or water pollution rules for specific industrial sectors. One rule, involving industrial laundries, was proposed in 1997. Two others involving centralized waste treatment facilities and transportation equipment cleaning had panels in 1997 and were proposed in 1998 (see table above). The EPA regularly makes panel reports available to the public at the time of rule proposal.

For these effluent guidelines, the panel process has either already brought relief to the affected small businesses in the proposal or has established the groundwork for providing relief in the final rule. In the case of the industrial laundries rule, based on comments from the Office of Advocacy in the panel and confirmatory comments from the industry, EPA recalculated its estimate of the pollutant loadings that it projected would be reduced by the regulation. Advocacy objected to the EPA methodology as inappropriate, and the EPA more recently agreed with Advocacy's approach. As a result, the EPA can now consider less burdensome regulation or no regulations for all the industrial laundries, which include over 1,000 small business facilities. And this change can be done without sacrificing any public policy or environmental safety objectives.

Similarly, in the other two effluent guidelines rulemaking, Advocacy, in its role as a panel member, identified other pollutant loadings estimation problems. In the case of transportation equipment cleaning facilities, the EPA estimated high pollutant loadings due to pollutants, which Advocacy identified were due to several pesticides—some of which were banned in the United States. This cast doubt on the EPA estimates. Industry representatives subsequently confirmed the EPA's miscalculation. As in

the laundry rule, this information would permit the agency to reduce the stringency of the requirements. During the panel process, one of the trade association representatives recommended that the agency exempt certain containers from the scope of the rule. Only Advocacy made this recommendation in the panel report. The agency, upon reconsideration of the data, agreed to exempt these containers from the proposed rule.

With regard to centralized waste treatment facilities, Advocacy discovered some apparently anomalous pollutant data that exaggerated the size of the pollution problem being addressed by the rule. The agency is exploring this data issue and alternative methods of reducing the small business burdens.

Class V Underground Injection Wells

The EPA has proposed standards for certain shallow wells that accept certain forms of industrial wastes that could pose hazards to drinking water. These wells, classified as Class V underground injection wells, were the subject of a panel that ended in April 1998. The draft rule under consideration by the panel would potentially affect owners and operators of three categories of Class V injection wells in certain defined areas in communities that use ground water as a source of drinking water. The two largest categories of Class V wells subject to the draft of the proposed rule are motor vehicle waste and industrial wells.

The non-EPA members of the panel provided separate recommendations from the EPA panel members. The non-EPA members criticized the EPA-provided data, because the data failed to demonstrate that the agency's approach would yield environmental benefits. The non-EPA members recommended some less stringent approaches. The panel convened in 1997, finalized its work in April 1998, and a proposal was issued in January 1999. In the proposed rule, EPA co-proposed some of these less stringent alternatives recommended by panel members. However, the EPA has yet to issue a final rule.

Ground Water

In the last of the water pollution rules, the EPA convened a panel in 1998 to address ground water pollution. This rule affects water systems that use ground water as the source of drinking water. This rule is designed to establish minimum requirements for all ground water systems to ensure the safety of the ground water. The small entity representatives and the panel members reviewed the broad menu of requirements that EPA could impose on small water systems and concluded that EPA could provide maximum flexibility for such systems and still achieve the desired environmental goals. In particular, the small entity representatives generally opposed the disinfection requirements and the expensive new monitoring requirements, except for those water systems which demonstrate a significant possibility of microbiological contamination. A proposed rule is expected in late 1999.

Long Term 1 Enhanced Surface Water Treatment

In August 1998, a panel was convened to address water systems that have surface water for their water source. The draft rule, at the time of the convening of the panel, was designed to establish regulatory controls to address *cryptosporidium* and to revise filtration systems in public water treatment plants. The panel considered regulatory flexibility options such as strengthened combined-filter effluent-turbidity requirements, individual filter monitoring and reporting requirements, *cryptosporidium* removal requirements, and disinfection benchmarking requirements. This rule is expected to be proposed in late 1999.

If the EPA adopts the recommendations made by Advocacy in the water pollution regulations alone, Advocacy estimates that savings would be in excess of $100 million dollars per year, with about $50 million being attributable to revisions in the industrial laundries rule.

Air Pollution Panels

Nitrogen Oxides

In June 1998, a panel was convened for two related rulemakings under the Clean Air Act: Federal Implementation Plan for Regional Reductions of Nitrogen Oxides (FIP) and Rulemaking Responding to Petitions Under Section 126 of the Clean Air Act (Section 126). The FIP controls the emissions of nitrogen oxides (NOx) in 22 eastern states and the District of Columbia. The purpose of the FIP is to provide a federal "backstop" rule to assure that necessary reductions in NOx are achieved in the event that states do not adequately address ozone transport problems in their revised State Implementation Plans. These plans are required as a result of a related rulemaking, the Ozone Transport Assessment Group (OTAG) "SIP (State Implementation Plan) Call," which provides a "budget" of smog and NOx reductions that each of these eastern states (and D.C.) is required to achieve.

The Section 126 companion rule addressed the same ozone transport issues. However, the Section 126 rule is derived from Section 126 of the Clean Air Act that allows "downwind" states to petition EPA for relief from pollution being transported from upwind states. Because of the close relationship between these two rulemakings, panels were convened simultaneously, and Advocacy examined regulatory alternatives that would apply to both rulemakings.

The panel examined a number of regulatory alternatives, and as a result of this work, small businesses emitting under one ton per day of NOx were exempted from the provisions of both rulemakings, as was the entire lime kiln industry. In addition to this burden-reducing alternative, Advocacy worked closely with EPA to ensure that the proposed rules would solicit comment on other regulatory alternatives, including:

- additional types of small entity industry-based exemptions including an exemption for small cement kilns;
- allowing non-trading sources to opt into an emissions trading program;
- exempting certain electric generating units that only operate during certain peak hours in the summer; and
- allowing for smaller amounts of NOx reductions from small business that operate boilers.

Gasoline Emission Standards

The proposed rule would cover tier 2 light-duty vehicle and light-duty truck emission standards and heavy-duty gasoline engine standards. under the Clean Air Act.[52] Under Section 202(i) of the act, the rule would seek the reduction of emissions of non-methane hydrocarbons, nitrogen oxides, and carbon monoxide from certain light duty vehicles and light duty trucks by model year 2003. The goal of this section of the act is to protect air quality in mostly urban and nonattainment areas.

The Small Business Advocacy Review Panel became concerned about the adverse impact the new sulfur standards would have on small refiners and the related adverse impact on gasoline price competition. Primarily, the rule would require that gasoline refiners reduce the level of sulfur in their gasoline product in order to assist certain types of vehicles in reaching the new EPA emission standards. Sulfur damages the catalytic converters on these types of engines—hindering the effectiveness of pollution-reducing equipment.

Small business refineries (those employing less than 1,500 employees), as well as all refineries, will be required to reduce the sulfur content of their gasoline. The 30 parts per million standard that EPA was considering was expected to cause substantial economic harm on most of the small refiners. The panel considered the following two flexibility options for the small refiners:

1) Compliance delays for domestic small refiners in the form of an less stringent interim standard that lasts from 2004 until 2008.
2) Refiners that are unable to meet "final" sulfur levels in 2008 are given an opportunity to apply for a "hardship" period of two additional years to get their sulfur levels to the national standard.

A proposed rule was issued in late May 1999.

[52] 42 U.S.C. §§ 7401 *et seq*.

Community Right-To-Know Reporting for Gasoline Stations

Since 1987, the Office of Advocacy has been calling for the elimination of reporting requirements for gasoline stations under the EPCRA arguing that the EPA had adequate hazard information on gasoline stations and that hazards of storing gasoline were well known in local communities. The information provided on the EPCRA emergency and hazardous chemical forms (Tier II) is similar and comparable to information submitted to state underground storage tank offices on the underground storage tank notification form under Section 9002 of the Resource Conservation and Recovery Act.[53] As a result of Advocacy's intervention, a final rule was issued, relieving about 200,000 gasoline outlets nationwide from the over lapping reporting requirement. The EPA estimates that annual paperwork savings could easily exceed 550,000 annual paperwork hours, at a cost savings of $16 million annually. More importantly, reducing the number of reports did not eliminate any information that the communities need in order to protect themselves.

Toxic Release Inventory - Small Quantity Exemption

In April and May of 1998, Advocacy participated in an interagency working group with the OMB and EPA officials to examine ways to reduce Toxic Release Inventory (TRI) burdens on small businesses, including the creation of a new reporting form that would benefit small businesses that manufacture, process, or otherwise use TRI chemicals. Advocacy noted that the current Form A (small quantity) threshold could be raised from 500 pounds to 1,000 pounds, which would save businesses millions of dollars without sacrificing community right-to-know concerns. In fact, the EPA would retain 99.88 percent of information on the longer Form R for chemical hazards in the environment. The EPA convened a group of stakeholders to examine this and other burden reduction options. The agency did establish other burden reduction measures for the calendar year 1998 reports due in July 1999. The EPA also reports that use of the simplified Form A in 1997 (latest available data) had increased by 50 percent over 1996 due to the EPA's increased outreach and educational efforts in early 1997 to promote the use of the form. The Form A was developed in 1994 in response to an Advocacy initiative to reduce paperwork burdens for small businesses.

Architectural Coatings

In June 1998, the EPA finalized the architectural coatings rule, which regulates the volatile organic compound content of paints and coatings. Advocacy worked with the agency to lower the costs of the pollution reduction requirements. The EPA allowed exemptions of small volumes of paint, and the payment of lower cost emissions fees in lieu of more expensive reformulation costs for small quantities of paint formulations.

[53] 42 U.S.C. §§ 6901 *et seq*.

This was a very significant small business issue affecting hundreds of small paint manufacturers nationwide.

Federal Communications Commission

With the passage of the Telecommunications Act of 1996, the nature and goal of the Federal Communications Commission (FCC) has greatly changed. Furthermore, the different industries in telecommunications are converging with the advent of digital technologies. These changes have created unprecedented opportunity for small business but have also created many new regulations and burdens for small entities. The Office of Advocacy has been in the forefront of many FCC proceedings, especially the size-standard issue, which plays a crucial part in determining which applicants qualify for designated entity status for spectrum auction.

Broadband Deployment

On August 7, 1998, the Federal Communications Commission released a proposed rulemaking designed to encourage deployment of broadband facilities. Broadband facilities are capable of carrying high-speed, high-capacity data communications, which are most commonly used by the Internet.

Advocacy filed comments asserting that the FCC:

1) failed to identify and undertake a proper reasoned analysis on all classes of small entities;
2) failed to describe adequately the proposed reporting, recordkeeping, and other compliance requirements; and
3) failed to consider significant alternatives that could minimize the significant economic impact of the proposed rule.

Advocacy asserted that the proposed rules were probably written with large incumbent local exchange carriers (ILECs) in mind. The regulations proposed and the benefits derived are only appropriate if the regulated entity is a large ILEC. The insufficient regulatory flexibility analysis seemed to have been constructed to justify rather than analyze the proposal. Advocacy contended that this was not sufficient compliance with the RFA.

Customer Proprietary Network Information

The FCC released an order on April 24 designed to protect private and personal information about a customer's name, address, calling patterns, and calling plans—also known as customer proprietary network information. The FCC adopted very stringent and burdensome rules that required local telephone companies to maintain records and create safeguards that were far in excess of the statutory mandate. Advocacy filed an *ex parte* letter with the FCC on July 3,1998 raising the issue that the FCC's rule violated several statutory duties set forth in the Paperwork Reduction Act (PRA)[54].

[54] 44 U.S.C. §§ 3501 *et seq*.

Advocacy asserted that the FCC's PRA procedures were deficient because the FCC did not develop a specific, objectively supported estimate of burden; seek public comments on the accuracy of the agency's estimate of the burden of the proposed collection of information; nor evaluate whether the proposed collection is necessary and useful. Moreover, since the FCC changed the rule materially from the original proposal, Advocacy maintained that the FCC then had a duty to submit new data to the OMB in support of its PRA request for approval.

The FCC's estimates do not include the cost of upgrades for software and hardware, installation, personnel training and workload, professional skills required, or maintenance of database for different sized telecommunications carriers, especially small carriers that may not have computer equipment at all. Given the absence of any public record input from the industry due to the lack of adequate notice and opportunity to comment, the FCC's estimates were speculative at best and unreasonable at worst.

In summary, the FCC failed to meet the statutory requirements of the Administrative Procedure Act, the RFA, and the PRA. Separately, the violations for each one of the above laws was sufficient to find the second report and order arbitrary and capricious. Cumulatively, these were overwhelming grounds for the commission to vacate or stay the flag and audit requirements and issue a further notice of proposed rulemaking if it wished to impose mechanized safeguards.

Spectrum Auctions

The Office of Advocacy submitted a petition to deny in December, 1998 in response to the assignment applications for the Personal Communications Services (PCS) licenses from Air Gate Wireless to Cricket Holdings, a wholly-owned subsidiary of Leap Wireless International. Advocacy requested that the FCC deny the status of "very small business" to Leap, but did not object to the transfer of the licenses from AirGate to Leap/Cricket.

Advocacy asserted that neither Cricket nor Leap qualify as a "very small business," because, pursuant to the FCC's affiliation and attribution rules, and as judged by a totality of the circumstances, Leap is still an affiliate of QUALCOMM, its former parent company. Therefore, QUALCOMM's $2.1 billion revenue and $2.45 billion in assets are attributable to Leap, making Cricket and Leap ineligible to qualify as "entrepreneurs" or "very small businesses" for broadband PCS C and F Blocks. Leap would not be prohibited from acquiring AirGate's license, only prohibited from receiving 25 percent small business bidding credits and installment payments—federal benefits it does not deserve. However, Leap would be prohibited from participating in any re-auction of C and F Entrepreneurs

Block licenses because it does not meet the entry criteria of a maximum of $500 million in assets.

It was not Advocacy's intent to add to the tortured saga of C Block, nor to delay the deployment of a competitive wireless service to the public. There were, however, two greater concerns present in this case that go beyond C Block: 1) the danger of eviscerating the FCC's competitive bidding rules, causing even more difficulty for bona fide small businesses to compete as viable providers in auctionable services, and 2) a breach of the public interest when an unqualified person receives benefits from the federal government.

Based on the corporate structure of Leap, including its contractual relationships with QUALCOMM, the SBA would find an affiliate relationship between Leap and QUALCOMM because there is no clear fracture between the two firms. In brief:

1) The very existence of Leap was and continues to be predicated on QUALCOMM's existence.
2) There is substantial economic dependence through-out the relationship. Leap's operating funds, acquisition financing, assets, key officers and directors, contractual arrangements for equipment purchases, office space, administrative support all come from QUALCOMM. Leap is very dependent on QUALCOMM's success and continuing existence for its own survival.
3) The two companies have identical or substantially identical business or economic interests in the wireless telecommunications industry, particularly given that Leap now holds QUALCOMM's former interests in other PCS licensees, and the majority of Leap's shareholders, if not all, are also QUALCOMM shareholders.
4) Three of QUALCOMM's former officers, including one of its founders, are now officers and directors of Leap, each with considerable stock holdings and/or options in both companies. Cumulatively, these are very strong affiliate relationships that indicate control or the potential of QUALCOMM to control Leap under the SBA's and the FCC's rules.

Leap's interpretation and use of the Publicly-Traded Corporation (PTC) exception as a means to avoid the FCC's affiliation and attribution rules was unreasonable given long-standing FCC policy and provisions under federal law to promote small business participation. The rule had also been incorrectly applied to determine small business eligibility. First, the plain language of the PTC exception rule indicates that it was adopted for a very narrow purpose, for "Competitive Bidding Procedures for Broadband PCS." Second, the rule is not applicable for defining small business eligibility given explicit language in the fifth report and order.

Advocacy also asserted that Leap did not qualify under the PTC exception as drafted for several reasons. The PTC exception is only for publicly-traded corporations with widely dispersed voting power. Leap's stock was not widely-dispersed because QUALCOMM stock holders held substantially all of Leap's stock and a nucleus of nine people effectively control Leap's stock. More importantly, the inherent nature of Leap's status as a spin-off company does not warrant application of the provisions set forth by the Commission obviously intended to aid nascent publicly traded corporations.

Interestingly, the Leap prospectus filed with the SEC reveals a deep and continuing relationship between the directors and officers of Leap Wireless and the directors and officers of QUALCOMM, which points to a unity of interest and control. Leap's officers and directors have a continuing relationship with QUALCOMM given considerable stock holdings in QUALCOMM, and possibly, continuing employee benefits under QUALCOMM's compensation for senior executives.

Significantly, by its own admission, QUALCOMM has considerable, and thus impermissible, influence over Leap. Based on the inherent nature of Leap as a spin-off from QUALCOMM, common stock and management interests between Leap and QUALCOMM's directors and officers, source of Leap's assets, source of operating capital, source of investment capital, and multiple contractual arrangements, Leap is an affiliate of QUALCOMM under a totality of circumstances. Considering the entire web of relationships, it stretches the imagination to believe that the potential for control does not exist. Therefore, Advocacy requested that the FCC take every possible measure, within its control, to preserve the integrity of its small business rules and deny Cricket/Leap's request for "very small business" designation under the FCC's rules.

Access Charge Reform

Advocacy applauded the FCC's decision to reconsider its decision in its Access Charge Reform proceeding. Advocacy had reminded the FCC of its statutory duty under the RFA to ascertain the practical small entity impact of Bell Atlantic's and Ameritech's pricing flexibility proposals, in addition to MCI's Emergency Petition, with a view to mitigating economic harm to all classes of small entities.

Although Advocacy did not comment whether or not there should be further reductions in access charges, it did, however, make a recommendation. If further access charge reductions are to be made by the commission, given the inadequacies of the current scheme, Advocacy urged the FCC to order interchange carriers (IXCs) to reduce rates for all end users proportionately to the access charge savings the IXCs receive. Advocacy urged the FCC to take every measure to ensure that small business consumers are not handicapped further.

The Office of Advocacy further requested the FCC to condition any reductions of access charges on the pass-through of IXC savings to each class of customer, including small business consumers. The FCC was encouraged to do a complete regulatory flexibility analysis of all small entity impacts—especially the impacts on small business consumers. This was particularly important since supplemental evidence, submitted by the public for the record, documented that small businesses had been disproportionately harmed and unfairly burdened by earlier access charge reforms ordered by the FCC.

Allocation of New Toll Free Numbers

In comments to the FCC, Advocacy detailed the significant economic impact that the roll out of the new 877 toll free code would have on small Responsible Organizations ("RespOrgs") and small business toll free subscribers. Primarily, Advocacy was concerned that the FCC's "first come, first served" method of number allocation, while well-intended, would not in fact result in fair access to the database. The reality was that large firms had the resources to tie up access to the database, effectively blocking RespOrgs access. The “first come, first served” concept would in fact distort allocation of the new numbers and reward the resource rich entities. Advocacy was also concerned about the conflict of interest inherent in the structure of larger toll free carriers and their RespOrg affiliates/subsidiaries.

Advocacy asked the FCC to eliminate the database access problems on the grounds that they were erecting market entry barriers and rendering the deployment of 877 grossly inefficient and patently unfair. Other entities made comments similar to Advocacy’s. Advocacy further urged the FCC to correct several material deficiencies in the FRFA, and to clarify significant portions of its order for the benefit of small businesses and future roll outs.

Advocacy also raised a question as to an inconsistency between the FCC's order and its pleading in a lawsuit before the United States Court of Appeals for the District of Columbia Circuit.[55] In these proceedings, the FCC had set forth two conflicting explanations for the application of its "first-come, first-served" allocation process for new toll free codes. In Advocacy’s view, the inconsistency raised serious questions about the FCC's compliance with the Administrative Procedure Act and the RFA, and whether its rules actually minimize the adverse impact on small businesses that it alleges. This inconsistency also raises significant confusion as to exactly what would be the rights and responsibilities of subscribers and RespOrgs.

[55] ResponseTrak Call Center’s Emergency Request for Stay before the United States Court of Appeals for the District of Columbia Circuit, *ResponseTrak Call Centers v. FCC*, No. 98-1195 (D.C. Cir. April 16, 1998).

General Services Administration

(See Department of Defense)

National Aeronautics and Space Administration

(See Department of Defense)

Securities and Exchange Commission

The Office of Advocacy and the Securities and Exchange Commission (SEC) continued their close working relationship in 1998 to improve regulatory compliance assistance for small businesses and small entities in many ways. The SEC continues to embody the spirit and intent of the RFA in the following ways: 1) publishing IRFA's and FRFA's for all rulemakings with potential impact upon small entities; 2) holding small business town hall meetings around the country requesting small business input on SEC actions and initiatives; 3) working with state securities regulators to ensure that federal/state oversight of small business corporate offerings are not conflicting or unduly burdensome; and 4) hosting the Annual Government-Business Forum on Small Business Capital Formation (forum).

In 1998, the SEC continued its outreach to the small business community by holding four small business town hall meetings in Austin, Texas, Las Vegas, Nevada, Salt Lake City, Utah, and Cleveland, Ohio. To date more than a dozen small business town hall meetings have been held by the SEC around the country and have been hosted by SEC Commissioners and top SEC officials. The SBA has participated in all of the town hall meetings.

In addition, the SEC held its annual forum in Chicago, Illinois in September 1998. This forum brings together the small business community, small business policy experts, academia and government officials to draft recommendations on improving the regulatory/legislative climate for small business capital formation. The recommendations are voted on by the attendees and sent to federal regulatory agencies and Congress. The SEC receives significant input on its current and past regulatory proposals from the small business attendees of the forum.

Microcap Fraud

The SEC issued a series of proposed regulatory actions that were intended to deter fraudulent activities in securities markets. Three specific rulemakings under this initiative were: "Initiation or Resumption of Quotations Without Specified Information (Rule 15c(2)(11))," "Seed Capital Rule (Rule 504 of Regulation D)," and "Addressing the Abuses of Form S-8 by Companies Using Consultants To Raise Capital."

The Office of Advocacy met with staff of the SEC on these rulemakings prior to their publication in the *Federal Register* and offered RFA and substantive guidance on their impact on small entity communities. Since state securities regulators also regulate small corporate securities, the Office of Advocacy consulted and advised the state securities regulators on the impact of the proposals on small entities. As the proposed rules were published for public comment, the SBA had significant outreach to

the small business community in order to generate comments on the proposals. Advocacy also provided extensive assistance to the SEC for the preparation of the publication of the final rules anticipated in early 1999.

Regulation of Securities Offerings

The SEC proposed a monumental rulemaking to overhaul the regulation of offering and selling securities by companies. The SEC requested Advocacy guidance on the rulemaking prior to publication and on SEC's request for an alternative small business size standard under the proposal. The Office of Advocacy met with the SEC staff and arranged meetings with the SBA's Office of Size Standards to formulate size standards appropriate for the small business community for raising capital in the equity markets. Advocacy also commented on the draft version of the IRFA before its publication with the proposed rule. In addition, Advocacy has been working with the SEC to reach out to the small business community for comment on the overall proposal and the initiatives affecting small entities.

Exemptive Offerings Pursuant to Compensatory Arrangements

In February of 1998 the SEC proposed to amend Rule 701, "Exemptive Offerings Pursuant to Compensatory Arrangements" that permits small companies an exemption from securities registration under the Securities Act of 1933[56] when they offer and sell stock to their employees. The proposal was designed to make the rule more accessible and to broaden the exemption amounts so that more private businesses could use securities to compensate their employees and others providing important services to their operations. The Office of Advocacy provided comments on the proposal and assisted the SEC in outreach to the small business community.

As the SEC continues to maintain high standards in implementing the RFA and reaching out to small entities to participate in the regulatory process in 1998, Advocacy has provided extensive informal and formal guidance and resources to the SEC on the development of regulatory proposals. This close-working relationship has enhanced small entities' access to our capital markets while maintaining critical investor protections.

[56] 15 U.S.C. §§ 77a *et seq*.

CONCLUSION

In calendar year 1998, the Office of Advocacy has witnessed renewed interest in the RFA by federal agencies. The work that the SBREFA has triggered in the regulatory community is bearing results. The full impact of the SBREFA, however, is yet to unfold. A cultural change is underway that will produce more reasoned regulations to address environmental, safety, and other important social problems without harming the economy. Calendar year 1998 is likely to be only a precursor of what is yet to come.

APPENDIX A: REGULATORY COMMENTS FILED BY THE OFFICE OF ADVOCACY IN 1998

Date	*Agency*	*Comment Subject*
01/07/98	U.S. District Court	*Amicus Curiae* in support of plaintiff's cross motion for summary judgment and in opposition to the defendants' motion for summary judgment. *Northwest Mining Association v. Babbitt, et al.*, case.
01/13/98	FRA	Memorandum on draft initial regulatory flexibility analysis and certification for use of locomotive horns at grade crossings.
01/23/98	OSHA	OSHA requested that the Office of Advocacy waive the SBREFA panel requirements for a negotiated rule for steel erection. On January 23, 1998, the Chief Counsel for Advocacy, after consulting with the administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget and affected small entities, granted OSHA's request to waive the panel.
02/03/98	FDA	Initial regulatory flexibility analysis of the proposed rule for dietary supplements containing ephedrine alkaloids. 62 Fed. Reg. 30,678 (June 4, 1997); Docket No. 95N-0304.
02/13/98	EPA	Groundwater disinfection rule; SBREFA Small Business Advocacy Panel under Section 609(b) of the RFA, as amended by the SBREFA.
02/17/98	FCC	Reply comments in support of the petition for rulemaking in the matter of access charge reform, CC Docket No. 96-262; price cap performance review for local exchange carriers, CC Docket No. 94-1; transport rate structure and pricing, CC Docket No. 91-213; end user common line charges, CC Docket No. 95-72.
02/20/98	AMS	RFA Certification of the proposed rule in changes in fees for federal meat grading and certification services. 62 Fed. Reg. 68,232, (December 31, 1997).
02/23/98	EPA	Proposed renewal request for the Office of Management and Budget; alternate threshold for low annual reportable amounts; toxic release inventory reporting. No. 1070-0143 (EPA ICR No. 1704.05). 62 Fed. Reg. 67,358 (December 24, 1997); Administrative Record No. 187; Docket Control No. OPPTS-0029.
03/03/98	FCC	Applauding the FCC's recent inquiry into the billing practices of the nation's largest interexchange carriers, AT&T, MCI, and Sprint. In re access charge reform, CC Docket No.96-262; price cap performance

Date	*Agency*	*Comment Subject*
		review for local exchange carriers, CC Docket No. 94-1; transport rate structure and pricing, CC Docket No. 91-213; end user common line charges, CC Docket No. 95-72.
03/04/98	EPA	Comments on draft proposed rule to exclude gasoline retail stations from the community right-to-know reporting requirements.
03/05/98	OSHA	Proposed rule on occupational exposure to tuberculosis encouraging OSHA to coordinate with existing federal, state, local, and private sector health care programs to ensure that the most effective approach for controlling the spread of TB is developed. 62 Fed. Reg. 54,160 (October 17, 1997).
03/17/98	FCC	In the matter of toll free service access codes written *Ex Parte* presentation on adverse economic impact on small businesses resulting from proposed April 5 implementation of 877.
03/25/98	FCC	*Ex Parte* comment - In re toll free service access codes, CC Docket No. 95-155.
04/03/98	FCC	Notice of *Ex Parte* presentation in a non-restricted proceeding.
04/14/98	LOC	The Library of Congress does not have to comply with the RFA. In accordance with 5 U.S.C. Section 601(1), the RFA defines the term "agency" as defined in 5 U.S.C. Section 551(1). Since the Library of Congress does not fall within the definition of "agency," it does not have to comply with the RFA.
04/15/98	EPA	RFA certification for national emission standards for hazardous air pollutants; proposed standards for hazardous air pollutants emissions for the Portland cement manufacturing industry. 63 Fed Reg. 14,182 (March 24, 1998).
04/15/98	HCFA	RFA requirements; petition for amendment of the final rule on surety bond and capitalization requirements for home health care agencies. 63 Fed. Reg. 292 (January 5, 1998); 63 Fed. Reg. 10,730; 63 Fed. Reg. 10,732 (March 4, 1998); file code HCFA-1152-FC.
04/17/98	EPA	Report of the SBREFA Small Business Advocacy Review Panel convened for EPA's proposed rulemaking on the underground injection control regulations for Class V injection wells.
04/17/98	EPA	Federal implementation plans to reduce the regional transport of ozone in the eastern United States; findings of significant contribution and

Date	*Agency*	*Comment Subject*
		rulemaking on Section 126 petitions from eight northeastern states for purposes of reducing interstate ozone transport: SBREFA Small Business Advocacy Review Panels.
04/17/98	MMS	Proposed rule on post lease operations concerning questioning the Minerals Management Service's certification and provides guidance on the type of threshold analysis that is necessary for determining whether a proposal will have a significant economic impact on a substantial number of small entities. 63 Fed. Reg. 7,335 (February 13, 1998).
04/20/98	NIST	Final rule under the Fastener Quality Act to allow for the use of quality assurance systems as a permissible alternative to the National Institute of Standards and Technology and the Department of Commerce's overall product testing and accreditation system for the fastener industry. 62 Fed.Reg. 18,259 (April 14, 1998).
04/23/98	EPA	Burden Reduction for small businesses currently subject to TRI Reporting requirements; Vice President’s announcement during Small Business Week.
04/24/98	NOAA	Draft Consideration of the economic effects and potential alternatives to the 1997 quotas on the Atlantic large coastal shark fishery.
04/27/98	EPA	Proposed revision of Form 2C, industrial permitting application; need for revised rulemaking schedule.
04/27/98	EPA	Comments on draft proposed rule to exclude gasoline retail stations from the community right-to-know reporting requirements.
04/28/98	CPSC	Request for comments concerning the toxicity, exposure, bio-availability, and environmental effects of flame retardant chemicals that may be suitable for use in residential upholstered furniture. 63 Fed. Reg. 13,017 (March 17, 1998).
05/04/98	FCC	Petition for reconsideration of the fourth report and order for toll free service access codes, CC Docket. No. 95-155.
05/05/98	EPA	Response to notification letter regarding long term 1 enhanced surface water treatment and filter backwash recycling; SBREFA Small Business Advocacy Review Panels.
05/05/98	EPA	Response to notification letter regarding: National Primary Drinking Water Regulation for Radon; SBREFA Small Business Advocacy Review Panels.

Date	*Agency*	*Comment Subject*
05/19/98	AMS	Small business impact of the proposed rule for milk in the New England and other marketing areas. 63 Fed. Reg. 4,802 (January 30, 1998).
05/22/98	FCC	Processing of set-aside 888 numbers for subscribers holding corresponding 800 numbers, CC Docket 95-155.
05/27/98	DOT	Proposed rule for transportation for individuals with disabilities. 63 Fed. Reg. 14,560 (March 25, 1998).
05/28/98	FCC	Notice of *Ex Parte* meeting with Dan Phythyon, Chief of the Wireless Telecommunications Bureau, FCC, regarding personal communications services C block June 8th election date.
06/01/98	NASA	Proposed and final rules on revisions to the Federal Acquisitions Regulation supplement on performance-based contracting and other miscellaneous revisions. 63 Fed. Reg. 9,953 (February 27, 1998); 63 Fed. Reg. 23,414 (April 29, 1998); 63 Fed. Reg. 27,859 (May 21, 1998); 63 Fed. Reg. 12,997 (March 17, 1998); 63 Fed. Reg. 12,992 (March 17, 1998); 63 Fed. Reg. 13,133 (March 18, 1998); 63 Fed. Reg. 17,339 (April 9, 1998); 63 Fed. Reg. 28,285 (May 22, 1998).
06/10/98	FDA	Proposed rule for labeling fresh unpasteurized juices. 63 Fed. Reg. 20,486 (April 24, 1998).
06/15/98	FCC	Reply to opposition to petition for reconsideration of the fourth report and order in the matter of Toll Free Service Access Codes, CC Docket No. 95-155.
06/15/98	HCFA	Final rule for the schedule of per-beneficiary limitations on home health agency costs (interim payment system final rule). 63 Fed. Reg. 15,718 (March 31, 1998).
06/24/98	NOAA	Fisheries off west coast states and in the Western Pacific; Western Pacific crustacean fisheries; bank area specific harvest guidelines. 63 Fed. Reg. 31,406 (June 9, 1998).
07/15/98	FCC	Notice of *Ex Parte* presentation in non-restricted proceedings; *In re* toll free service access codes, CC Docket No. 95-155; Access charge reform, CC Docket. No. 96-262; federal-state joint board on universal service, CC Docket. No. 96-45; Implementation of the Telecommunications Act of 1996: telecommunications carriers' use of customer proprietary network information and other customer information, CC Docket. No. 96-115; and performance measurements and reporting requirements for operations

Date	*Agency*	*Comment Subject*
		support system, interconnection, and operator services and directory assistance, CC Docket. No. 98-56, RM-9101.
07/23/98	FCC	Notice of *Ex Parte* presentation in a non-restricted proceeding; *In re* implementation of the Telecommunications Act of 1996: telecommunications carriers' use of customer proprietary network information and other customer information, CC Docket No. 96-115. Fed. Reg. 20,326 (April 24, 1998)
08/13/98	DOD	RFA compliance pertaining to the notice regarding proposed implementation of the defense table of official distances in the DOD personal property program. 63 Fed. Reg. 31,761 (June 10, 1998) .
08/18/98	EPA	Preliminary comments on EPA's proposed effluent guidelines for the transportation equipment cleaning industry.
08/21/98	OIRA	Comments on the EPA's request for Office of management and Budget paperwork approval for Form A ("Short Form") for toxic chemical release inventory reporting.
08/21/98	EPA	Rulemaking responding to petitions under Section 126 of the Clean Air Act. SBREFA Small Business Advocacy Review Panels.
08/21/98	EPA	The federal implementation plans for regional reductions of nitrogen oxides. SBREFA Small Business Advocacy Review Panels.
08/27/98	FSIS	Notice of procedural change in the meat, poultry and egg products labeling review process – elimination of appointments with label courier/expediter firms. 63 Fed. Reg. 40,010 (July 27, 1998).
09/10/98	FCC	*Ex Parte* presentation in a non-restricted proceeding; *In re* amendment of part 1 of the commission's rules - competitive bidding procedures, WT Docket No. 97-82.
09/10/98	HCFA	Regulatory flexibility analysis of the proposed rule revising the payment policies for portable x-ray providers under the physician fee schedule for calendar year 1999. 63 Fed. Reg. 30,818 (June 5, 1998).
09/16/98	OSHA	Responding to OSHA's September 1 notification that they are planning to propose a rule on safety and health program that may have a significant impact on a substantial number of small businesses.
09/17/98	FCC	*Ex Parte* filing; subscriber list information, CC Docket No. 96-115.

Date	*Agency*	*Comment Subject*
09/21/98	DOD	Response to Military Traffic Management command letter dated September 8, 1998, addressing the proposed implementation of the defense table of official distances and compliance with the regulatory flexibility act. 63 Fed. Reg. 31,761 (June 10, 1998).
09/21/98	IRS	Comments on proposed rulemaking to clarify the application of the unrelated business income tax to tax exempt organizations. CC:DOM:CORP:R (Reg. 121268-97).
09/23/98	OSHA	Clarifying data needs in preparing for a forthcoming Small Business Advocacy Review Panel on OSHA's safety and health program rule.
09/23/98	EPA	Report of the Small Business Advocacy Review Panel convened on effluent limitations guidelines and standards for the transportation equipment cleaning industry.
09/25/98	FCC	Deployment of Wireline Services Offering Advanced Telecommunications Services, CC Docket No. 98-147.
10/07/98	FCC	Notice of *Ex Parte* presentation in non-restricted proceedings; *In re* access charge reform, CC Docket 96-262; and truth-in-billing and billing format, CC Docket No. 98-170.
10/14/98	FDA	Structure or function claims/statements made for dietary supplements. 63 Fed. Reg. 23,624 (April 29, 1998).
10/16/98	FCC	Reply comments on deployment of wireline services offering advanced telecommunications services, CC Docket No. 98-147.
10/26/98	FCC	Access charge reform, CC Docket No. 96-262; price cap performance review for local exchange carriers, CC Docket No. 94-1; Consumer Federation of America et al., petition for rulemaking, RM-9210; MCI Telecommunications Corp., emergency petition for prescription, CC Docket No. 97-250.
11/02/98	HCFA	Implementation of Balanced Budget Act of 1997 requirements relating to home medical equipment suppliers: inherent reasonableness and competitive bidding demonstration projects.
11/06/98	FCC	GTE Telephone Operating Companies (GTOC) Tariff No. 1, GTOC Transmittal No. 1148, CC Docket No. 98-79.
11/18/98	HCFA	Failure to comply with the RFA in promulgating the final rule on revisions to payment policies and adjustments to the relative unites under the

Date	*Agency*	*Comment Subject*
		physician fee schedule for calendar year 1999. 63 Fed. Reg. 58,814 (November 2,1998).
11/20/98	FCC	Notice of *Ex Parte* in non-restricted proceedings. *In re* federal-state joint board on universal service, CC Docket No. 96-45.
12/02/98	APHIS	Proposed rule for importation of orchids in growing media. CC Docket No. 98-035-163; Fed. Reg. 46,403 (September 1, 1998).
12/08/98	EPA	Comments on draft rule on persistent bioaccumalative toxics under the toxics release inventory reporting program.
12/14/98	FCC	Application for assignment of broadband PCS C and F block licenses to Cricket Holdings, Inc., a Wholly-owned Subsidiary of Leap Wireless International Inc., FCC public notice DA 98-2319; AirGate Wireless, L.L.C., (FCC File No. 0000002035); Jacksonville Wireless, L.P. (FCC File No. 0000002167).
12/18/98	OMB	Discussing the paperwork impact on small businesses resulting from the bidding forms associated with HCFA's competitive bidding demonstration project.
12/23/98	OMB	Comments regarding the paperwork impact of the HCFA's OASIS regulations. 62 Fed. Reg. 11,035 (March 10, 1997).

APPENDIX B: 1998 ECONOMIC ANALYSES, REGULATORY STUDIES, AND RELATED MATERIALS

Date	*Agency*	*Title*
01/29/98	OSHA	Comments on the OSHA tuberculosis rule IRFA.
02/17/98	Advocacy	IRFA and Certification Checklists.
02/19/98	USDA	Comments on the preliminary regulatory impact analysis of federal milk marketing order consolidation and reform.
03/26/98	EPA	Comments on the Portland cement manufacturing regulatory analysis.
03/26/98	Advocacy	*The Regulatory Flexibility Act: An Implementation Guide for Federal Agencies.*
04/15/98	Advocacy	Regulatory materials provided to Office of Advocacy's regulatory flexibility economics and analysis roundtable.
05/07/98	NMFS	Baseline Economic Information on Commercial and Finfish Industry.
06/15/98	NMFS	Evaluation of the NMFS Analysis of Economic Effects Associated with proposed rule to Reduce the Harvest of Large Coastal Shark.
06/01/98	NASA	Proposed and Final Rules on revisions to the Federal Acquisitions Regulation supplement on performance-based contracting and other miscellaneous revisions.
07/24/98	NMFS	Sample National Economic Impact Analysis On the Directed Large Coastal Shark Fishery.
08/17/98	Advocacy	*Protecting Fish and Fisherman – Economic Analysis under the RFA*, a paper presented at the American Fisheries Society Annual Meeting.
09/09/98	OSHA	OSHA Health & Safety Rule RFA §609(b)(1) letter, a technical review of the OSHA data submission.
10/02/98	Advocacy	*The Requirements of the Regulatory Flexibility Act – An*

Date	*Agency*	*Title*
		Opportunity for Analytical Advance, a paper presented at an Annual meeting on Economic modeling.
10/26/98	HUD	Report to the Department of Housing and Urban Development's (HUD) regarding HUD's request for comment on their proposed determination that the rule to control lead-based paint hazards in federally owned residential property and housing receiving federal assistance does not impose significant economic impacts on a substantial number of small entities.
11/10/98	OSHA	OSHA Health and Safety Rule – Compliance Cost Assumptions Analysis.
11/17/98	Advocacy	Facts on the Size and Growth of the Federal Regulatory Establishment.
12/08/98	OSHA	Benefits and Costs of the Health and Safety Rule.

APPENDIX C: TESTIMONY OF THE CHIEF COUNSEL ON SBREFA

TESTIMONY
of
JERE W. GLOVER
CHIEF COUNSEL FOR ADVOCACY
U.S. Small Business Administration

before the

SUBCOMMITTEE ON GOVERNMENT PROGRAMS AND OVERSIGHT
and the
SUBCOMMITTEE ON REGULATORY REFORM AND PAPERWORK REDUCTION

COMMITTEE ON SMALL BUSINESS
UNITED STATES HOUSE OF REPRESENTATIVES

March 18, 1998

on
Analysis of small business advocacy review panels as required under the Small Business Regulatory Enforcement Fairness Act of 1996

Good morning Chairwoman Kelly, Chairman Bartlett and members of the Committee. I am Jere W. Glover, Chief Counsel for Advocacy of the U.S. Small Business Administration.(1) I am pleased to appear before your subcommittees to discuss the small business advocacy review panels, as required under the Small Business Regulatory Enforcement Fairness Act of 1996, (SBREFA) and their impact on reducing the regulatory burdens on small business.(2)

The Small Business Regulatory Enforcement Fairness Act was a tremendous victory for small business and common sense government. The new law reinforces and strengthens the Regulatory Flexibility Act-one of the most important laws for assuring regulations are developed in an environment that welcomes small business participation. For the Office of Advocacy, the amendments of the Regulatory Flexibility Act have provided new leverage in our efforts to change the regulatory culture of Federal agencies.

One of the significant changes mandated by SBREFA is the requirement that the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA) convene a small business advocacy review panel prior to the publishing of a proposed rule that will have an significant impact on small entities.(3) This requirement allows for important input from small entities at a critical point in the development of a Federal regulation.

The Small Business Regulatory Burden Continues

Traditionally, America's small businesses have been concerned that government does not fully understand and appreciate the cost and burden regulations impose on their operations. With the passage of the Small Business Regulatory Enforcement Fairness Act in 1996, Congress and the Administration reaffirmed a commitment to address small business concerns about regulatory and paperwork burdens.

As the Chief Counsel for Advocacy, I am charged by Congress to represent the interests of small businesses before the Federal government. A significant part of that mandate is improving the rulemaking process. We continue to find that agencies are more likely to minimize the burden on small entities while meeting their regulatory objectives if they involve small businesses and the Office of Advocacy early in the rulemaking process.

Advocacy's Office of Economic Research has surveyed the impact of regulations on small firms.(4) A 1994 study commissioned by Advocacy (5) revealed that small firms are disproportionately burdened by the cost of regulatory compliance. In fact, the burden of compliance is as much as 50 percent more for small businesses than their larger counterparts.(6)

This cost differential gives larger firms a competitive advantage in the marketplace, a result at odds with the national interest in maintaining a viable, dynamic and progressive role for small business in the economy. Efforts to lessen the burden on small business are not "special treatment." Rather they level the playing field and are sound public policy.

The Panel Process is a Valuable Tool

SBREFA addressed the regulatory burden problem by mandating the creation of small business advocacy review panels for rules issued by EPA and OSHA. As I testified last year, the panel requirement is an important addition to the Regulatory Flexibility Act because it inserts small businesses into the process early - before an agency issues a proposed rule. The panel process is only one component of a comprehensive package of reforms taken by this Administration, this Congress and the Chief Counsel for Advocacy to reduce the regulatory burden. Significant accomplishments include: 1) expanding the jurisdiction of the Regulatory Flexibility Act to interpretive rules of the Internal Revenue Service that impose a collection of information requirement; 2) the Vice President's reinvention initiative to make regulations more reasonable and responsive; 3) the President's March, 1995, enforcement memo to agencies, encouraging more common sense enforcement activities; and 4) SBREFA's strengthening of the amicus authority of the Chief Counsel and allowing judicial review of agency compliance with certain provisions of the Regulatory Flexibility Act. It is too early to measure the impact of these measures on the overall burden on small business, but we are beginning to see changes in agency behavior.

Based on our experience thus far, Advocacy has found that review panels seem to have enhanced the decision making process. Discussions about serious policy decisions between key agency officials and businesses within an affected industry are a real eye-opener for all participants. Federal agency staff must discuss and explain their proposed regulation with real small businesses under circumstances that promote dialogue. Small businesses in turn learn about the agency objectives and legal requirements. I strongly believe that this process will continue to be a useful and viable method of early identification of small business concerns, promulgation of more effective rules and meaningful reduction in the unnecessary regulatory burden on small business.

The process is new. It is therefore arguably premature to attempt a definitive analysis of the overall impact on the regulatory process since there have only been six rules for which agencies have convened panels. What I can report is that, at a minimum, agency consideration of regulatory alternatives and small business impacts has been improved. The whole purpose of the panel process is to ensure that the agencies involved begin looking at the potential small business implications of their proposed rulemaking early on in the process - and that seems to be working.

EPA and OSHA Compliance

Since the enactment of SBREFA, five panels have been completed by EPA and one completed by OSHA. We are encouraged by the progress that has been made and the efforts which the agencies are putting forth. We will continue to work hard with these agencies to ensure that the needs of the small business community and the mandates of SBREFA are met without compromising other public policy objectives such as health and environmental safety.

The first panel report authored by EPA, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) and the Chief Counsel under SBREFA concerned a rulemaking that would set emissions controls for manufacturers of diesel engines for equipment that does not operate on the road (for example, farm equipment and forklifts). The panel made five recommendations for regulatory relief based on ten options presented

by the small entities to the EPA Administrator. The agency found it could adopt these five options, save money for the affected businesses, and still achieve virtually the same amount of emissions reductions. The key issue here is that the impacts of the proposed rule on small entities could be mitigated while achieving the same amount of emissions reductions. We were pleased that all five suggestions were included in the agency's proposed rule, published on September 24, 1997.

The EPA also convened a panel for a water pollution rule affecting industrial laundries. The EPA proposed a small business exemption that would exclude approximately seven percent of all laundries, based on the inconsequential discharges of these smallest facilities. With Advocacy's efforts, the panel and EPA agreed to consider and solicit comment both on a no-regulation option and, in the alternative, a wider small business exemption. In its analysis, the agency found that even unregulated discharges from the smallest facilities had little or no effect on the environment, thus demonstrating that the "one size fits all" approach to regulation does not necessarily advance environmental improvements. This rule was proposed in December, 1997.

The third EPA panel involved water permits for stormwater dischargers (phase II). The rule was proposed on January 8, 1998. This rule had already benefited from the recommendations of a large group of affected entities who were members of an advisory committee subject to the Federal Advisory Committee Act (FACA). However, even after the extensive two year FACA process (many of the same small entity advisors participating in this process were consulted by the EPA review panel), the SBREFA panel process yielded an important change to the proposed rule that would relieve small business facilities from performing a complex and costly environmental assessment, which they were ill-equipped to perform. Instead, the agency's objective was achieved by requiring the state permit authorities to perform the analyses. In the proposal, small business facilities now need only complete a simple checklist of stormwater related items. EPA still gets the information it needs to accomplish its objectives, but without unduly burdening small entities.

Although EPA has completed panels for two other rules, the proposals have yet to be published. The impact of these panels will not be known until the proposals that are developed in response to the small business and panel recommendations are published.

One problem that arose frequently in the panel process with EPA is one that I hope will diminish as we fine tune the process. Advocacy and the small entity representatives were constantly seeking additional information from EPA in each of the panel proceedings. In more than one rulemaking, EPA initially presented the small entity representatives with only the EPA proposal, without any significant regulatory alternatives to consider. Subsequent to our request, the agency quickly remedied these omissions. In several rules, EPA offered no information about the cost of the regulation or competing alternatives.

This type of information is generally essential to informed analysis of the rule and alternatives. The Federal panel members (consisting of representatives from the Office of Information and Regulatory Affairs, EPA, and the Office of Advocacy) frequently debate the need to provide additional materials to the small entity representatives and the panelists, materials that would shed light on economic impacts, and expected environmental results. In recent panels, we have been more successful about gathering the material in a timely manner for the small entity representatives and panel members. We believe we have been making significant progress in addressing this issue, and are hopeful that the information problem we have been encountering will be less severe as the small entity analysis becomes institutionalized.

As the GAO report indicates, only one panel has been held for an OSHA rulemaking. The panel was conducted for a rule to limit Occupational Exposure to Tuberculosis (TB). OSHA published the proposed rule on October 17, 1997. The small entities subject to the proposed rule include hospitals, homeless shelters and nursing homes.

Small entities raised several significant concerns during the panel process, including the complexity of the rule and the need for OSHA to coordinate its efforts with existing voluntary and regulatory health and safety programs designed to control infectious disease. OSHA responded to some of the issues raised by small entities during the panel process, including further clarification of key terms, definitions, and certain requirements. Advocacy submitted comments for the record on the proposed rule in which it continued to encourage OSHA to consider many of the alternatives raised by small entities to ensure that a policy is developed which will protect workers without

increasing the risk to the general public and take into account the compliance problems that might ensue due to the limited resources of organizations such as homeless shelters and hospices.

The TB rule had already progressed significantly through the regulatory process and was already in draft form at the time SBREFA was implemented. Thus, the panel and small business entities had to address a rule on which OSHA had already developed clear views on how to address worker exposure to TB. Unfortunately, the proposed rule does not contain as many fundamental changes as we would have liked.

In the future, Advocacy anticipates that OSHA will facilitate outreach to small businesses in the earliest stages of the rulemaking process. For example, OSHA is now developing a rule which will require businesses to adopt Safety and Health Programs. For this rule, OSHA and Advocacy jointly held a series of small business outreach meetings in the summer of 1997. Advocacy is optimistic that the early small business input will greatly assist OSHA in developing the rule.

Identifying small entities, including small businesses, to be consulted by the panel is another challenge. It is often difficult to find potentially affected small businesses which are willing and able to devote the time and effort it takes to become a part of the small business panel. By definition, small entities do not have the luxury of administrative staff that can work on projects unrelated directly to the work of the enterprise. To be effective, small entity participants in the panels require time - time away from their businesses to review a draft of the rule, the economic analysis and appropriate risk assessment materials that demonstrate the need for the rule. The activity is labor intensive and time consuming. Nevertheless, I am confident that, as the panel process progresses and small businesses witness the impact which their involvement can have, small businesses will view participation as a cost-effective activity.

And while trade associations and legal consultants are a good source of expertise, they cannot fully substitute for the "hands-on" insights small entities can bring to the process.

Both agencies are learning quickly that the SBREFA requirements are both beneficial to their rulemaking process and to the small business community. The ultimate question to ask when judging the success of the panels and the compliance of the agencies is: Did the panel process result in the agency making changes to the rule that mitigated impacts on small entities without compromising the rule's objective? We have seen some changes to proposed regulations, and as more proposed rules become final regulations, we will be better able to answer this question and judge the success of these panels. In the meantime, the work for members of the panel will remain labor intensive until the process becomes institutionalized and more efficient. Advocacy looks forward to continuing to work with EPA and OSHA.

Conclusion

Participation in the development of regulations is an important right of small businesses. Recognizing that small business is the major source of competition and economic growth, Congress established through the RFA a process to design regulations that will help achieve statutory and regulatory goals efficiently without harming or imposing undue burdens on the major source of competition in the nation's economy - small business. The passage of the Small Business Regulatory Enforcement Fairness Act has cemented this important role of small businesses. The SBREFA requirement for small business advocacy review panels guarantees that two major federal regulatory agencies will seriously consider the impact of regulation on small businesses at the earliest possible stages.

From Advocacy's perspective, the process has great potential. We and the agencies are learning together how to make it as effective as Congress envisioned it could be. We are learning how to identify information and analyses needed, what materials can effectively communicate the issues to small entity representatives, how to streamline the process and improve the economic and policy impact analyses and how to maximize the input from small entities. The process will help institutionalize within regulatory agencies the kind of analyses that substantiate regulatory solutions without 1) unduly burdening small business, 2) erecting barriers to competition or 3) discouraging the introduction of beneficial products and processes.

As for the balance of the government, judicial review of agency compliance with certain provisions of the RFA provides a major incentive for agencies to improve their impact analyses and, thus, avoid court challenges to their regulations.

Finally, I wish to express appreciation for the work of the GAO staff who worked on this report. Their investigation generated some lively and very productive exchanges of information. We truly appreciated their insights on legislative history and the objectivity with which they approached their task.

ENDNOTES

1. The Office of Advocacy, established by Public Law 94-305, is an independent office charged with representing the views and interests of small businesses before the Federal government. By law, the Chief Counsel is appointed by the President from the private sector and confirmed by the Senate. The Chief Counsel's comments are his own and do not necessarily reflect the views of the Administration or the Small Business Administration.
2. Pub. L. 104-121
3. Pub. L. 104-121, § 241; 5 U.S.C. § 609 (b) - (e)
4. See Appendix A for a listing.
5. A Survey of Regulatory Burdens, Report to the Office of Advocacy, U.S. Small Business Administration, Thomas D. Hopkins and Diversified Research, Inc., June 1995.
6. The Changing Burden of Regulation, Paperwork, and Tax Compliance on Small Business: A Report to Congress, Office of Advocacy, U.S. Small Business Administration, October 1995.

APPENDIX
OFFICE OF ADVOCACY
Economic Research Studies: Regulatory Impact on Small Business

On-Going Economic Research

Studies of the Impacts of Federal Regulations, Paperwork, And Tax Requirements for Small Business (Draft final, May 1997), Henry Beale, Microeconomic Applications, Washington, D.C. The studies examines the relative cost of regulations in small vs. large firms in a representative group of regs from EPA, OSHA, EPA, and the IRS. Cost ratios are expressed on a common basis.

Contract Bundling and Small Business: Effects of the Federal Acquisition Streamlining Act on Small Business (Draft final February 1997), Eagle Eye Consulting, Arlington, VA. This study concluded that while the dollar volume of federal awards to small firms has risen slightly from FY91-FY95, the number of small firms receiving awards is declining. However, awards to 8(a) firms have been rising.

Enforcement Penalties Against Small Businesses
Kelly Lear, Bloomington, Indiana (Ph.D Dissertation). (To be completed in 1997). This thesis is examining the size of the penalties on businesses by firm size to determine if any systematic relationships exist between the size of the penalties by government regulators and the size of the business they are regulating.

Published Economic Research

Utility Deregulation and the Effects on Small Business, J.W. Wilson and Associates, Washington, D.C. (1996). This study concluded that small firms will be adversely effected by stranded costs as the result of competition in the market for electricity. Because of their lack of bargaining power, small firms may not be able to bid for the lower cost electric rates of alternative suppliers.

A Survey of Regulatory Burdens, Diversified Research, Irvington, N.Y. (June, 1995). This nationally representative study surveyed 360 firms in 15 industries to determine the regulatory burden across 4 firm sizes. It concluded that firms with 1-4 employees could be spending up to $32,000 per employee for regulatory costs, compared with $17,000 per employee for firms with more than 50 employees. IRS paperwork burden accounted for much of the differential.

Profiles of Regulatory Costs, Thomas D. Hopkins, Rochester, N.Y. (November, 1995). This study attempted to measure total regulatory costs on both households and businesses. It concluded that, despite data limitations, small firms face greater regulatory burdens. Process regulation accounted for some 40 percent of regulatory costs, while environmental regulations accounted for about a quarter of regulatory costs.

Cost-Effective Regulation by EPA and Small Business Impacts, Christopher R. Allen, Henry B.R. Beale, Robert E. Burt, Cynthia Pantazis, and Kathleen A. Shaver (1992), Microeconomic Applications, Inc., Washington, D.C. The Regulatory Flexibility Act requires the Environmental Protection Agency and other federal agencies to consider reasonable alternatives that may minimize burdens on small entities while achieving statutory objectives. For various reasons, effects on small entities may not be adequately addressed through cost-effective regulatory alternatives. This research, which focuses on eight case studies involving EPA regulations, explores factors and problems contributing to this outcome, and also provides examples of successful EPA regulatory flexibility analysis.

The Impact of Telephone Deregulation on Small Business, J.A. Montanye (1988), Cornell University Group, Inc., Falls Church, VA. This study looks at prevailing regulatory issues at the state and federal levels in the telecommunications industry in the late 1980s. It attempts to assess the potential impact of regulatory reform on the price and availability of telecommunications services used by small businesses. Case studies of the telecommunications regulation experiences of Nebraska, Vermont, and Colorado are included.

An Analysis of Closures of Industries in SIC 24 and 25 As a Result of Proposed OSHA Regulations, Policy Planning and Evaluation, Inc. (1988), Vienna, VA. Regulations proposed in 1988 by the Occupational Safety and Health Administration to revise standards for air contaminants would require many industries to purchase and install air pollution control equipment. Some firms may be excessively burdened by the costs of complying with the regulations, even to the point of closing down. This paper focuses on the tests used to determine the financial ability of firms in SIC 24 (lumber and wood products) and SIC 25 (furniture and fixtures) to bear the costs imposed by the proposed OSHA regulations.

Pension Laws and Regulations Affecting Small Business Plan Decisions, Anthony J. Sulvetta, Christopher M. Niemczewski, and Martha A. Solt (1986), Jutin Research Associates, Washington, D.C. This study finds that frequently changing pension laws and regulations require small firms to hire specialists, which increases costs and deters firms from offering pension plans. Burdensome regulations include reporting and disclosure requirements; top-heavy rules; and fiduciary, funding, and vesting requirements.

Comments on the Environmental Protection Agency's Effluent Limitation Guidelines for the Organic Chemicals, Plastics, and Synthetic Fiber Industries, Charles Marshall (1985), JACA Corporation, Fort Washington, PA. The analysis shows that 23 percent of 636 affected facilities would close as a result of these effluent guidelines, compared to the Environmental Protection Agency's estimate of 15 percent. The difference was largely due to EPA's failure to consider financial variability within categories and its overstatement of affordability.

Comments on EPA's Effluent Limitation Guidelines for the Pesticide Chemicals Industry, Charles Marshall (1984), JACA Corporation, Fort Washington, PA. The report recommends that the Environmental Protection Agency adopt alternatives to the zero discharge rule for the pesticide formulation and packaging industry. Suggested spray treatment is not widely available. In addition, compliance costs are more than double the EPA estimates.

Disproportional Burden of Regulations on Small Business Economies of Scale in Regulatory Compliance: Evidence of the Differential Impacts of Regulation by Firm Size, Todd A. Morrison (1984), Jack Faucett Associates, Inc., Chevy Chase, MD. A disproportionate burden is placed on small business by federal regulations, according to this report. Studies of 14 regulations in 150 three-digit SIC code industries showed that the median small firm experiences an average cost per employee greater than three times the large firm.

Comments on EPA's Effluent Limitation Guidelines Covering the Lead-Acid Battery Manufacturing Industry, Charles Marshall (1984), JACA Corporation, Fort Washington, PA. The study recommends that the U.S. Environmental Protection Agency develop a regulatory flexibility analysis (RFA) for this standard due to the magnitude of differential control costs. The regulatory alternatives used in this RFA should include alternative discharge levels.

Comments on the Environmental Protection Agency's Effluent Limitation Guidelines for the Metal Molding and Casting Industries, Charles Marshall (1984), JACA Corporation, Fort Washington, PA. This study lists 13 processes which should be excluded from regulation. It recommends that sensitivity analyses should be conducted by the Environmental Protection Agency and that financial ratio thresholds should be tested. Zero discharge should not be required unless attainable.

Comments on the Environmental Protection Agency's Effluent Limitation Guidelines for the Nonferrous Metals Manufacturing Industries, Charles Marshall (1984), JACA Corporation, Fort Washington, PA. This study concludes that ammonia should not be included in the Environmental Protection Agency's effluent limitation guidelines. A requirement for filtration cutoff of 10,000 tons per year for secondary aluminum plants is recommended. No allowance is made in the study for the variation in cost structure between plants and industry types.

A Preliminary Examination of the Quality and Performance of S-18 Offerings and Securities, Alfred E. Osborne, Jr. (1983), A.E. Osborne Associates, Sherman Oaks, CA. In 1979, the Securities and Exchange Commission, through the adoption of Form S-18, announced simplified registration and reporting requirements for the sale of securities -- not to exceed $5 million -- by certain small issuers. This preliminary study looked at the experiences of six companies that filed S-18 registrations and were subsequently listed in the Wall Street Journal. It sought to determine: (1) the investment quality of the issues; (2) the costs of effecting S-18 offerings of securities in contrast to comparable initial public offerings; and (3) the aftermarket performance of each company.

The Relationship Between Asset Size and the Number of Shareholders for SEC Reporting Companies, Alfred E. Osborne, Jr. (1983), A.E. Osborne Associates, Sherman Oaks, CA. For small firms, unlike for large firms, the costs of meeting SEC reporting requirements outweigh the benefit to shareholders of the reported information. This study recommends the establishment of exemptions from SEC reporting requirements based on asset size.

Report of the Use of the Rule 146 Exemption in Capital Formation, Ulysses Lupien and John Matthews (1983), Securities and Exchange Commission, Office of Economic Research, Washington, D.C. The Rule 146 exemption from registration requirements of the Securities Act of 1933 was available from 1974 to 1982. It was adopted to provide great certainty in exempted nonpublic offerings by establishing more objective standards upon which stock issuers could rely in raising capital.

Asset Size and Alternative Policy Criteria in Securities Regulation, Alfred E. Osborne, Jr. (1983), A.E. Osborne Associates, Sherman Oaks, CA. The study surveyed 265 firms, approximately 77 percent of all small high technology firms reporting to the SEC in 1977. Three-quarters of the firms had stock market values below their book values. The average value of holding per shareholder was one-tenth that of the New York Stock Exchange's average.

An Estimate of Compliance Costs Under the Periodic Reporting Requirements of the Securities and Exchange Commission for Small High-Technology Companies, Alfred E. Osborne, Jr. (1983), A.E. Osborne Associates, Sherman Oaks, CA. This study of 265 companies showed that reporting costs for quarterly 10-Q and annual 10-K reports were over $50,000. The disclosure requirements impose a heavier burden on small companies than on large companies because the costs are largely fixed.

Impact of Environmental Regulations on Small Business, Nathaniel Greenfield (1982), Booz Allen and Hamilton, Inc., Bethesda, MD. As federal regulatory agencies have fulfilled their congressional mandates, some regulators, concerned about the disproportionate impact of regulation on small businesses, have designed special exemptions for small firms. The research described in this report attempts to ascertain whether government environmental regulations have in fact had disproportionate adverse effects on smaller manufacturing firms. The analysis examines a sample of industries to find out how well small firms have fared relative to larger firms over time.

An Analysis of the Use of Regulation a for Small Public Offerings, William C. Dale, Ulysses G. Lupien, and Robert E. Zweig (1982), Securities and Exchange Commission, Directorate of Economic Research, Washington, D.C. The Regulation A exemption from the registration provisions of the Securities Act of 1933 provides small

stock issuers with a simplified procedure for selling a limited dollar amount of securities in a public offering without having to incur the full expense and delay of the complete registration process. Using data from SEC filings, this study examines the general operation of Regulation A by focusing on the characteristics of the issuers and offerings using the exemption. It also examines the effects of the increase in the Regulation A ceiling amount that came into effect in 1978.

Federal Regulation of Small Business, William A. Brock and David S. Evans (1982), Chicago Economic Research Association, Evanston, IL. As a result of legislation passed in the late 1960s and early 1970s, federal regulation of businesses increased dramatically. During the 1970s the federal regulatory budget grew sixfold and federal regulatory employment nearly tripled. Also during the 1970s, evidence indicated that uniform application of regulatory requirements increases the minimum size of firms that can compete effectively in the regulated market. This study describes small business' role in the economy and examines the impact of federal regulations and taxes on businesses of different sizes.

Complying with Government Requirements: The Costs to Small and Larger Businesses, Roland J. Cole and Paul Sommers (1981), Battelle Memorial Institute, Human Affairs Research Center, Seattle, WA. During the 1970s, government requirements increased the cost of doing business in all industries. Government requirements pose special problems for small businesses because they cost more per dollar of revenue than in moderate-sized or large firms. This report assesses the cost impact of government regulations on small business.

The Impact of Federal Regulations on Small Firms in the New England Fishing Industry, Catherine P. Wiggins (1981), University of New Haven, West Haven, CT. This study examined the effects of the Fishery Conservation and Management Act of 1976, and found that it reversed the decline of the New England fishing industry by reducing competition from foreign vessels. However, small fishermen did not have a voice in fishery management planning.

Small Business and Motor Carrier Regulatory Reform, Michael W. Pustay (1981), Texas A&M University, College Station, TX. This research explores the impacts on the small business community of U.S. Interstate Commerce Commission (ICC) regulation of the interstate motor carrier industry and recent reforms of ICC motor carrier regulation. Three areas are examined in depth: the provision of motor carrier service to small businesses in small communities, protection for small businesses from discriminatory pricing by ICC-regulated motor carriers, and ensuring equal access for small businesses to the services of small contract carriers.

Improving Economic Impact Analyses of Government Regulations on Small Business, Charles R. Marshall (1981), JACA Corporation, Fort Washington, PA. The study concludes that the costs of required reporting, recordkeeping, and testing should be included in cost estimates. These costs are higher per unit for smaller firms. The study recommends the model plant approach.

Steps to Ensure the Viability of the Residential Fuel Oil Distribution System, Peter Bos (1980), Resource Planning Associates, Cambridge, MA. In the 1970s, there were about 8,000 heating oil dealers in the United States, most of them small independent businesses. This study took a look at some of the problems then threatening the viability of these small firms -- such as tighter supplier credit, decreasing market share, and anticompetitive government regulation -- and offered some strategies to alleviate the negative impact of these trends.

The Impact of Federal Regulations on the Small Coal Mine in Appalachia, Bernard Davis and Raymond Ferrell (1980), Appalachian Development Center, Morehead, KY. This study addresses two specific issues influencing the production of coal from small mines: (1) the direct costs and other effects of governmental regulation and deregulation on coal operators in general, and (2) the effects of governmental policies on the productivity by size class of small coal mines. Permitting costs, productivity data, and operating and compliance costs were examined for sample groups of small mines in Kentucky.

Industry Rivalry and Strategy in the Regulatory Process, Sharon Oster (1980), Yale University, New Haven, CT. The study shows how a firm might support regulations that differentially damage its rivals. A firm's incentive to engage in strategic regulatory investments depends on the nature of the proposed regulation and barriers to entry and mobility.

Costs of Compliance in Small and Moderate-Sized Businesses, Roland J. Cole and Paul Sommers (1980), Battelle Memorial Institute, Seattle, WA. This paper considers theoretical reasons for expecting small businesses to have more variable -- but on average proportionately higher -- costs of compliance with government requirements than moderate-sized businesses. Small businesses are more likely not to comply because they are less likely to be detected, but when they do comply, their costs are proportionately higher. Empirical tests of this theory for a Washington State sample of small- and moderate-sized businesses confirm that small businesses report higher mean costs but greater variability across firms.

Analysis of Regulatory Cost on Establishment Size for the Small Business Administration, Michael E. Simon and L. Ross Beard (1979), Arthur Andersen & Company, Washington, D.C. The purpose of this study was to analyze the cost impact of government regulation by size of business. The electrical machinery industry was selected as an industry that showed meaningful regulatory cost trends, incremental costs of regulations, as well as trends in regulatory costs, are shown by business size.

APPENDIX D: THE REGULATORY FLEXIBILITY ACT

The following text of the Regulatory Flexibility Act is taken from Title 5 of the United States Code, sections 601–612. The Regulatory Flexibility Act was originally passed in 1980 (P.L. 96-354) and was amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (P.L. 104-121).

§ 601. Definitions

For purposes of this chapter—

(1) the term "agency" means an agency as defined in section 551(1) of this title;

(2) the term "rule" means any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b) of this title, or any other law, including any rule of general applicability governing Federal grants to State and local governments for which the agency provides an opportunity for notice and public comment, except that the term "rule" does not include a rule of particular applicability relating to rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services, or allowances therefor or to valuations, costs or accounting, or practices relating to such rates, wages, structures, prices, appliances, services, or allowances;

(3) the term "small business" has the same meaning as the term "small business concern" under section 3 of the Small Business Act, unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register;

(4) the term "small organization" means any not-for-profit enterprise which is independently owned and operated and is not dominant in its field, unless an agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the Federal Register;

(5) the term "small governmental jurisdiction" means governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand, unless an agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and which are based on such factors as location in rural or sparsely populated areas or limited revenues due to the population of such jurisdiction, and publishes such definition(s) in the Federal Register;

(6) the term "small entity" shall have the same meaning as the terms "small business", "small organization" and "small governmental jurisdiction" defined in paragraphs (3), (4) and (5) of this section; and

(7) the term "collection of information"—

(A) means the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for either—

(i) answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, 10 or more persons, other than agencies, instrumentalities, or employees of the United States; or

(ii) answers to questions posed to agencies, instrumentalities, or employees of the United States which are to be used for general statistical purposes; and

(B) shall not include a collection of information described under section 3518(c)(1) of title 44, United States Code.

(8) Recordkeeping requirement.—The term "recordkeeping requirement" means a requirement imposed by an agency on persons to maintain specified records.

§ 602. Regulatory agenda

(a) During the months of October and April of each year, each agency shall publish in the Federal Register a regulatory flexibility agenda which shall contain—

(1) a brief description of the subject area of any rule which the agency expects to propose or promulgate which is likely to have a significant economic impact on a substantial number of small entities;

(2) a summary of the nature of any such rule under consideration for each subject area listed in the agenda pursuant to paragraph (1), the objectives and legal basis for the issuance of the rule, and an approximate schedule for completing action on any rule for which the agency has issued a general notice of proposed rulemaking; and

(3) the name and telephone number of an agency official knowledgeable concerning the items listed in paragraph (1).

(b) Each regulatory flexibility agenda shall be transmitted to the Chief Counsel for Advocacy of the Small Business Administration for comment, if any.
(c) Each agency shall endeavor to provide notice of each regulatory flexibility agenda to small entities or their representatives through direct notification or publication of the agenda in publications likely to be obtained by such small entities and shall invite comments upon each subject area on the agenda.
(d) Nothing in this section precludes an agency from considering or acting on any matter not included in a regulatory flexibility agenda, or requires an agency to consider or act on any matter listed in such agenda.

§ 603. Initial regulatory flexibility analysis
(a) Whenever an agency is required by section 553 of this title, or any other law, to publish general notice of proposed rulemaking for any proposed rule, or publishes a notice of proposed rulemaking for an interpretative rule involving the internal revenue laws of the United States, the agency shall prepare and make available for public comment an initial regulatory flexibility analysis. Such analysis shall describe the impact of the proposed rule on small entities. The initial regulatory flexibility analysis or a summary shall be published in the Federal Register at the time of the publication of general notice of proposed rulemaking for the rule. The agency shall transmit a copy of the initial regulatory flexibility analysis to the Chief Counsel for Advocacy of the Small Business Administration. In the case of an interpretative rule involving the internal revenue laws of the United States, this chapter applies to interpretative rules published in the Federal Register for codification in the Code of Federal Regulations, but only to the extent that such interpretative rules impose on small entities a collection of information requirement.
(b) Each initial regulatory flexibility analysis required under this section shall contain—
(1) a description of the reasons why action by the agency is being considered;
(2) a succinct statement of the objectives of, and legal basis for, the proposed rule;
(3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
(4) a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
(5) an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule.
(c) Each initial regulatory flexibility analysis shall also contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. Consistent with the stated objectives of applicable statutes, the analysis shall discuss significant alternatives such as—
(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;
(2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;
(3) the use of performance rather than design standards; and
(4) an exemption from coverage of the rule, or any part thereof, for such small entities.

§ 604. Final regulatory flexibility analysis
(a) When an agency promulgates a final rule under section 553 of this title, after being required by that section or any other law to publish a general notice of proposed rulemaking, or promulgates a final interpretative rule involving the internal revenue laws of the United States as described in section 603(a), the agency shall prepare a final regulatory flexibility analysis. Each final regulatory flexibility analysis shall contain—
(1) a succinct statement of the need for, and objectives of, the rule;
(2) a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
(3) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
(4) a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
(5) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal

reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.
(b) The agency shall make copies of the final regulatory flexibility analysis available to members of the public and shall publish in the Federal Register such analysis or a summary thereof.

§ 605. Avoidance of duplicative or unnecessary analyses
(a) Any Federal agency may perform the analyses required by sections 602, 603, and 604 of this title in conjunction with or as a part of any other agenda or analysis required by any other law if such other analysis satisfies the provisions of such sections.
(b) Sections 603 and 604 of this title shall not apply to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. If the head of the agency makes a certification under the preceding sentence, the agency shall publish such certification in the Federal Register at the time of publication of general notice of proposed rulemaking for the rule or at the time of publication of the final rule, along with a statement providing the factual basis for such certification. The agency shall provide such certification and statement to the Chief Counsel for Advocacy of the Small Business Administration.
(c) In order to avoid duplicative action, an agency may consider a series of closely related rules as one rule for the purposes of sections 602, 603, 604 and 610 of this title.

§ 606. Effect on other law
The requirements of sections 603 and 604 of this title do not alter in any manner standards otherwise applicable by law to agency action.

§ 607. Preparation of analyses
In complying with the provisions of sections 603 and 604 of this title, an agency may provide either a quantifiable or numerical description of the effects of a proposed rule or alternatives to the proposed rule, or more general descriptive statements if quantification is not practicable or reliable.

§ 608. Procedure for waiver or delay of completion
(a) An agency head may waive or delay the completion of some or all of the requirements of section 603 of this title by publishing in the Federal Register, not later than the date of publication of the final rule, a written finding, with reasons therefor, that the final rule is being promulgated in response to an emergency that makes compliance or timely compliance with the provisions of section 603 of this title impracticable.
(b) Except as provided in section 605(b), an agency head may not waive the requirements of section 604 of this title. An agency head may delay the completion of the requirements of section 604 of this title for a period of not more than one hundred and eighty days after the date of publication in the Federal Register of a final rule by publishing in the Federal Register, not later than such date of publication, a written finding, with reasons therefor, that the final rule is being promulgated in response to an emergency that makes timely compliance with the provisions of section 604 of this title impracticable. If the agency has not prepared a final regulatory analysis pursuant to section 604 of this title within one hundred and eighty days from the date of publication of the final rule, such rule shall lapse and have no effect. Such rule shall not be repromulgated until a final regulatory flexibility analysis has been completed by the agency.

§ 609. Procedures for gathering comments
(a) When any rule is promulgated which will have a significant economic impact on a substantial number of small entities, the head of the agency promulgating the rule or the official of the agency with statutory responsibility for the promulgation of the rule shall assure that small entities have been given an opportunity to participate in the rulemaking for the rule through the reasonable use of techniques such as—
(1) the inclusion in an advanced notice of proposed rulemaking, if issued, of a statement that the proposed rule may have a significant economic effect on a substantial number of small entities;
(2) the publication of general notice of proposed rulemaking in publications likely to be obtained by small entities;
(3) the direct notification of interested small entities;
(4) the conduct of open conferences or public hearings concerning the rule for small entities including soliciting and receiving comments over computer networks; and
(5) the adoption or modification of agency procedural rules to reduce the cost or complexity of participation in the rulemaking by small entities.

(b) Prior to publication of an initial regulatory flexibility analysis which a covered agency is required to conduct by this chapter—

(1) a covered agency shall notify the Chief Counsel for Advocacy of the Small Business Administration and provide the Chief Counsel with information on the potential impacts of the proposed rule on small entities and the type of small entities that might be affected;

(2) not later than 15 days after the date of receipt of the materials described in paragraph (1), the Chief Counsel shall identify individuals representative of affected small entities for the purpose of obtaining advice and recommendations from those individuals about the potential impacts of the proposed rule;

(3) the agency shall convene a review panel for such rule consisting wholly of full time Federal employees of the office within the agency responsible for carrying out the proposed rule, the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Chief Counsel;

(4) the panel shall review any material the agency has prepared in connection with this chapter, including any draft proposed rule, collect advice and recommendations of each individual small entity representative identified by the agency after consultation with the Chief Counsel, on issues related to subsections 603(b), paragraphs (3), (4) and (5) and 603(c);

(5) not later than 60 days after the date a covered agency convenes a review panel pursuant to paragraph (3), the review panel shall report on the comments of the small entity representatives and its findings as to issues related to subsections 603(b), paragraphs (3), (4) and (5) and 603(c), provided that such report shall be made public as part of the rulemaking record; and

(6) where appropriate, the agency shall modify the proposed rule, the initial regulatory flexibility analysis or the decision on whether an initial regulatory flexibility analysis is required.

(c) An agency may in its discretion apply subsection (b) to rules that the agency intends to certify under subsection 605(b), but the agency believes may have a greater than de minimis impact on a substantial number of small entities.

(d) For purposes of this section, the term "covered agency" means the Environmental Protection Agency and the Occupational Safety and Health Administration of the Department of Labor.

(e) The Chief Counsel for Advocacy, in consultation with the individuals identified in subsection (b)(2), and with the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget, may waive the requirements of subsections (b)(3), (b)(4), and (b)(5) by including in the rulemaking record a written finding, with reasons therefor, that those requirements would not advance the effective participation of small entities in the rulemaking process. For purposes of this subsection, the factors to be considered in making such a finding are as follows:

(1) In developing a proposed rule, the extent to which the covered agency consulted with individuals representative of affected small entities with respect to the potential impacts of the rule and took such concerns into consideration.

(2) Special circumstances requiring prompt issuance of the rule.

(3) Whether the requirements of subsection (b) would provide the individuals identified in subsection (b)(2) with a competitive advantage relative to other small entities.

§ 610. Periodic review of rules

(a) Within one hundred and eighty days after the effective date of this chapter, each agency shall publish in the Federal Register a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities. Such plan may be amended by the agency at any time by publishing the revision in the Federal Register. The purpose of the review shall be to determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the rules upon a substantial number of such small entities. The plan shall provide for the review of all such agency rules existing on the effective date of this chapter within ten years of that date and for the review of such rules adopted after the effective date of this chapter within ten years of the publication of such rules as the final rule. If the head of the agency determines that completion of the review of existing rules is not feasible by the established date, he shall so certify in a statement published in the Federal Register and may extend the completion date by one year at a time for a total of not more than five years.

(b) In reviewing rules to minimize any significant economic impact of the rule on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the agency shall consider the following factors—

(1) the continued need for the rule;

(2) the nature of complaints or comments received concerning the rule from the public;

(3) the complexity of the rule;

(4) the extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and

(5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

(c) Each year, each agency shall publish in the Federal Register a list of the rules which have a significant economic impact on a substantial number of small entities, which are to be reviewed pursuant to this section during the succeeding twelve months. The list shall include a brief description of each rule and the need for and legal basis of such rule and shall invite public comment upon the rule.

§ 611. Judicial review

(a)(1) For any rule subject to this chapter, a small entity that is adversely affected or aggrieved by final agency action is entitled to judicial review of agency compliance with the requirements of sections 601, 604, 605(b), 608(b), and 610 in accordance with chapter 7. Agency compliance with sections 607 and 609(a) shall be judicially reviewable in connection with judicial review of section 604.

(2) Each court having jurisdiction to review such rule for compliance with section 553, or under any other provision of law, shall have jurisdiction to review any claims of noncompliance with sections 601, 604, 605(b), 608(b), and 610 in accordance with chapter 7. Agency compliance with sections 607 and 609(a) shall be judicially reviewable in connection with judicial review of section 604.

(3)(A) A small entity may seek such review during the period beginning on the date of final agency action and ending one year later, except that where a provision of law requires that an action challenging a final agency action be commenced before the expiration of one year, such lesser period shall apply to an action for judicial review under this section.

(B) In the case where an agency delays the issuance of a final regulatory flexibility analysis pursuant to section 608(b) of this chapter, an action for judicial review under this section shall be filed not later than—

(i) one year after the date the analysis is made available to the public, or

(ii) where a provision of law requires that an action challenging a final agency regulation be commenced before the expiration of the 1-year period, the number of days specified in such provision of law that is after the date the analysis is made available to the public.

(4) In granting any relief in an action under this section, the court shall order the agency to take corrective action consistent with this chapter and chapter 7, including, but not limited to—

(A) remanding the rule to the agency, and

(B) deferring the enforcement of the rule against small entities unless the court finds that continued enforcement of the rule is in the public interest.

(5) Nothing in this subsection shall be construed to limit the authority of any court to stay the effective date of any rule or provision thereof under any other provision of law or to grant any other relief in addition to the requirements of this section.

(b) In an action for the judicial review of a rule, the regulatory flexibility analysis for such rule, including an analysis prepared or corrected pursuant to paragraph (a)(4), shall constitute part of the entire record of agency action in connection with such review.

(c) Compliance or noncompliance by an agency with the provisions of this chapter shall be subject to judicial review only in accordance with this section.

(d) Nothing in this section bars judicial review of any other impact statement or similar analysis required by any other law if judicial review of such statement or analysis is otherwise permitted by law.

§ 612. Reports and intervention rights

(a) The Chief Counsel for Advocacy of the Small Business Administration shall monitor agency compliance with this chapter and shall report at least annually thereon to the President and to the Committees on the Judiciary and Small Business of the Senate and House of Representatives.

(b) The Chief Counsel for Advocacy of the Small Business Administration is authorized to appear as amicus curiae in any action brought in a court of the United States to review a rule. In any such action, the Chief Counsel is authorized to present his or her views with respect to compliance with this chapter, the adequacy of the rulemaking record with respect to small entities and the effect of the rule on small entities.

(c) A court of the United States shall grant the application of the Chief Counsel for Advocacy of the Small Business Administration to appear in any such action for the purposes described in subsection (b).