20 Years of the Regulatory Flexibility Act

Rulemaking in a Dynamic Economy

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To the President and Congress of the United States:

Twenty years ago, on September 19, 1980, Congress enacted the Regulatory Flexibility Act (RFA) mandating that agencies consider the impacts of regulatory proposals on small entities and determine in good faith whether there were equally effective alternatives that would make the regulatory burden on small business more equitable.

In 1996, Congress enacted the Small Business Regulatory Enforcement Fairness Act (SBREFA), amending the RFA in three significant ways. First, courts were given authority to review agency compliance with the RFA in appeals from agency final actions. Second, the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA) were required to convene small business advocacy review panels to consult with small entities when the agency believed it would have to prepare an initial regulatory flexibility analysis of the small entity impacts. Finally, the Chief Counsel for Advocacy's authority to file amicus curiae ("friend of the Court") briefs, authority first granted by the RFA in 1980, was reaffirmed and broadened.

This is the seventh report I have submitted since being nominated by the President and confirmed by the Senate in May 1994 as Chief Counsel for Advocacy. I am pleased to report that, although compliance with the RFA still remains somewhat uneven, improved agency compliance is very clearly under way. The Act has become measurably and significantly effective in achieving the law's objective, namely, more equitable regulations. Agencies are learning to do more in-depth and quality regulatory impact analyses and seeking more guidance on how to comply with the RFA.

The Office of Advocacy is also now able to estimate the compliance costs that small businesses will not have to incur as the result of regulatory changes made in response to Advocacy's recommendations and those of small business. These regulatory savings amounted to $20.6 billion for the three-year period 1998, 1999, and 2000 and resulted from markedly improved analyses of economic and scientific data urged upon the agencies by Advocacy and others. Agencies should be applauded for their willingness to change regulatory proposals after analyzing both burdensome impacts and alternatives that are equally effective in accomplishing public policy objectives. This, after all, was the result Congress intended when it enacted the RFA.

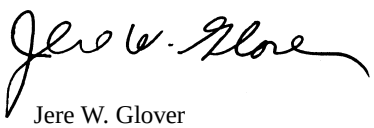
Since enactment of SBREFA, small entities have sought judicial review of agency compliance with the RFA. Not surprisingly, this development has been accompanied by increased agency interest in avoiding challenges to regulations. Last year we

reported a noticeable increase in agency requests for Advocacy's guidance on RFA compliance prior to publication of proposals for public comment. This phenomenon was not fleeting. Pre-proposal consultation with the Office of Advocacy has continued and expanded this year. We devoted about 4,300 professional hours this past year to pre-proposal work in addition to the estimated 4,900 hours spent on EPA and OSHA SBREFA panels. These hours also include consultations with the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget pursuant to an "Exchange of Letters" agreed to in January 1995. These consultations have become institutionalized in the close working relationship that has developed from our joint work on SBREFA small business advocacy review panels at EPA and OSHA.

On an informal basis, the Office of Advocacy has facilitated meetings for small businesspeople with congressional staff and with executive branch officials, convening ad hoc issue-specific meetings to discuss small business issues. Out of these meetings has emerged the realization that these discussions can lead to smarter regulations and directly benefit the work of regulatory agencies. However, the success of such meetings is directly influenced by the extent to which agency officials are willing to listen.

Not all agencies, however, are seeking consultations with the Office of Advocacy or small businesspeople prior to publishing or finalizing proposals, even though some level of outreach to the small business community is required by the RFA. Advocacy has had to critique agency impact analyses and RFA compliance deficiencies, including noncompliance with the Administrative Procedure Act (APA) and the Small Business Act. These criticisms are discussed in Appendix B to this report.

Despite this uneven performance, significant improvement is under way. As we approach a new Administration and a new Congress, I hope that the progress discussed in this report, marking the 20th anniversary of the RFA, establishes a baseline against which to measure future agency efforts to comply with the law and Advocacy's successes in reducing inequitable regulatory burdens on small business. I will be happy to answer any questions. Just contact me at 202/205-6533.



Jere W. Glover

Chief Counsel for Advocacy

January 2001

Contents

Abbreviations

ACE-Net	Access to Capital Electronic Network
AMS	Agricultural Marketing Service
APA	Administrative Procedure Act
APHIS	Animal and Plant Health Inspection Service
ATBCB	Architectural and Transportation Barriers Compliance Board
ATF	Bureau of Alcohol, Tobacco and Firearms
BHC	bank holding company
BLM	Bureau of Land Management
BPA	blanket purchase agreement
C.F.R.	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CMRA	commercial mail receiving agencies
DME	durable medical equipment
DMERC	durable medical equipment regional carrier
DOC	U.S. Department of Commerce
DOD	U.S. Department of Defense
DOI	U.S. Department of the Interior
DOJ	U.S. Department of Justice
DOL	U.S. Department of Labor
DOT	U.S. Department of Transportation
EA	economic area
EO	executive order
EPA	Environmental Protection Agency
ERISA	Employee Retirement, Income, and Security Act
FAA	Federal Aviation Administration
FAR	Federal Acquisition Regulation
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FDIC	Federal Deposit Insurance Corporation
FHC	financial holding company
FHWA	Federal Highway Administration
FMC	Fishery Management Council
FMCSA	Federal Motor Carrier Safety Administration

FNS	Food and Nutrition Service
FPI	Federal Prison Industries
FRA	Federal Railroad Administration
FRFA	final regulatory flexibility analysis
FRS	Federal Reserve System
FS	Forest Service
FSIS	Food Safety and Inspection Service
FSS	Federal Supply Schedules
FTC	Federal Trade Commission
FWS	Fish and Wildlife Service
GAO	General Accounting Office
GSA	General Services Administration
GWAC	government-wide agency contract
HAP	hazardous air pollutants
HCFA	Health Care Financing Administration
HHA	home health agencies
HHS	U.S. Department of Health and Human Services
HUD	U.S. Department of Housing and Urban Development
ICANN	Internet Corporation for Assigned Names and Numbers
IPS	interim payment system
IRFA	initial regulatory flexibility analysis
IRS	Internal Revenue Service
MACT	maximum achievable control technology
MMS	Minerals Management Service
MSHA	Mine Safety and Health Administration
NARA	National Archives and Records Administration
NASA	National Aeronautics and Space Administration
NHTSA	National Highway Traffic Safety Administration
NIST	National Institute of Standards and Technology
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NPRM	notice of proposed rulemaking
NPS	National Park Service
OASIS	outcome and assessment information set
OCC	Office of the Comptroller of the Currency

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
OTS	Office of Thrift Supervision
P.L.	Public Law
PCS	personal communications services
PMB	private mail box
PPS	prospective payment system
PRA	Paperwork Reduction Act
PRO-Net	Procurement Marketing and Access Network
PWBA	Pension and Welfare Benefits Administration
RFA	Regulatory Flexibility Act
RHC	rural health clinic
RSPA	Research and Special Programs Administration
SBA	Small Business Administration
SBREFA	Small Business Regulatory Enforcement Fairness Act
SBIC	small business investment company
SEC	Securities and Exchange Commission
STAWRS	state tax and wage reporting system
TLD	top level domain
USDA	U.S. Department of Agriculture
U.S.C.	United States Code
USPS	United States Postal Service
VA	U.S. Department of Veterans Affairs
WHCSB	White House Conference on Small Business
WIPO	World Intellectual Property Organization

Preface

On September 19, 1980, the U.S. Congress enacted the Regulatory Flexibility Act (RFA) to ensure that agencies considered the impact of their regulatory proposals on small business.[1] Congress made several findings that frame the overall policy objectives of the law. The most definitive are:

> "….the failure [by agencies] to recognize differences in the scale and resources of regulated entities has in numerous instances adversely affected competition in the marketplace, discouraged innovation and restricted improvements in productivity;
> …unnecessary regulations create entry barriers in many industries and discourage potential entrepreneurs from introducing beneficial products and services…."[2]

Stated simply, Congress did not want public policy to erect unnecessary barriers to competition; therefore, regulations should not have unintended anti-competitive consequences. Adverse consequences could be avoided if agencies considered the impact of regulations on small business and modified proposals to make them more equitable. It was Congress' intent that this be accomplished without compromising public policy objectives.

Over the last past 20 years, there has been significant turnover in policy decision-makers within the Congress, the White House and regulatory agencies. New statutory mandates have been enacted to address societal problems, many of which are complex and identified—as well as solved—by new technology and scientific knowledge. These changes complicate the task of ensuring that there is a consistent approach to complying with the RFA throughout the federal government, while at the same time giving deference to each regulatory agency's expert judgment in crafting regulations that fulfill its public policy mission.

> Has progress been made? Yes and no.
> Is the RFA accomplishing its objective? Yes and no.
> Is the RFA still needed? Definitively, yes.

Advocacy is of the view that the RFA is still significantly viable and may always be needed. In an economy that is churning and ever changing, in which new industries emerge or change and in which small business plays such a pivotal role in generating

1. 5 U.S.C. § 601 *et seq*.
2. 5 U.S.C. § 601 2(a), (4) and (5).

competition, the challenge to avoid unintended consequences from potentially burdensome regulations remains the same as it was in 1980.

The reasons the challenge remains the same are several. The government is called upon to address new problems. At the same time, government agencies face an ongoing challenge to craft wise solutions based on sound economic and scientific data, which, in many instances, may not be readily available without additional research. Developing creative solutions to regulatory problems requires appropriate training and resources. Finally, agencies charged by Congress to administer specific laws do not readily see or accept their statutory obligation under the RFA to do no harm to competition by their actions. As a consequence, they do not aggressively pursue analyses of less burdensome alternatives that may be equally effective in fulfilling their public responsibilities.

Are changes needed to the RFA? That remains for the readers of this report to answer. This report is intended to present a picture of what exists today that reflects the activities of the Office of Advocacy over the last 20 years.

Overview

A Brief History of the RFA

This report marks the 20th anniversary of the enactment of the RFA - an important milestone. To put the report's contents in perspective, a brief review of some legislative and related history is presented below (see “Important Dates,” page 4).

Creation of the Office of Advocacy

In June 1976, Congress created the Office of Advocacy to be headed by a Chief Counsel, appointed by the President from the private sector and confirmed by the Senate. Congress concluded that small businesses needed a voice in the councils of government —a voice that was both independent and credible—to ensure that big business' influence and well-funded lobbyists did not unduly influence public policy. The Chief Counsel's mandate, therefore, is to be an independent voice for small business in policy deliberations, a unique mission in the federal government, unlike any other. The law specifically required the Office of Advocacy to measure the costs and impacts of regulation on small business.

“On the regulations, I cannot say enough…somebody has to give us some zip to let it really rip.”—James D. McKevitt, National Federation of Independent Business, 1976

Enactment of the Regulatory Flexibility Act (RFA)

Studies on the costs and impacts of regulations did not, however, do enough to influence regulatory decisions. Consequently, in September 1980, Congress enacted the Regulatory Flexibility Act (RFA) which mandated that agencies consider the impact of their regulatory proposals on small entities, analyze equally effective alternatives and make their analyses available for public comment.

The law was not intended to create special treatment for small business. Congress intended that agencies consider impacts on small business to ensure that, in their efforts to fulfill their public responsibilities, their proposals did not have unintended anti-competitive impacts and that agencies explored less burdensome alternatives that were equally, or more, effective in resolving agency objectives.

“Total cost to the U.S. economy of Federal government paperwork requirements is estimated to be $100 billion per year. Private industry cost is $25 to $32 billion per year and it is estimated that 5 million small businesses pay $15 to $20 billion of the $100 billion total. Because of limited resources, small business is woefully ill-equipped to deal with rigid regulatory and paperwork requirements.” —Briefing book for the 1980 White House Conference on Small Business

The Office of Advocacy was given the responsibility for reporting annually to Congress and the President on agency compliance with this law.[3] The RFA also authorized the Chief Counsel to appear as *amicus curiae* (i.e. "friend of the court") in actions brought to review a rule.[4] These new responsibilities expanded the role of the Chief Counsel and the office to represent small business in the development of public policy. It was implicitly understood that the effectiveness of these responsibilities was contingent on how well the Chief Counsel asserted the independence that Congress bestowed on the office.

3. 5 U.S.C. § 612 (a).
4. 5 U.S.C. § 612 (b).

Important Dates in the Evolution of the RFA

This is a brief chronology of congressional and other actions that have structured or influenced the legal framework within which agencies function to comply with the RFA while fulfilling their statutory mandates. Some of the dates have been highlighted because of their importance.

June 1976	**Congress enacts Public Law 94-305, creating an Office of Advocacy** within the U.S. Small Business Administration charged, among other things, to "measure the direct costs and other effects of federal regulation on small businesses and make legislative and non-legislative proposals for eliminating excessive or unnecessary regulation of small businesses."
April 1980	The first White House Conference on Small Business calls for "sunset review" and economic impact analysis of regulations, and a regulatory review board including small firm representation.
Sept. 1980	**Congress passes the Regulatory Flexibility Act (RFA)**, requiring agencies to analyze the impact of proposed rules on small business, consider and analyze meaningful alternatives, and publish their analyses for public comment.
Oct. 1981	The Office of Advocacy reports on the first year of Regulatory Flexibility Act experience intestimony before the Subcommittee on Export Opportunities and Special Small Business Problems of the U.S. House Committee on Small Business.
Feb. 1983	Advocacy publishes first in the series of written annual reports on agency RFA implementation. Report shows spotty agency compliance.
Nov. 1986	Delegates to the second White House Conference on Small Business recommend strengthening RFA enforcement by, among other things, subjecting agency compliance to judicial review.
Sept. 1993	President Clinton issues Executive Order 12866, "Regulatory Planning and Review," requiring each federal agency to "tailor its regulations to impose the least burden on society, including businesses of different sizes…"
Apr. 1994	The General Accounting Office (GAO) issues a report on agencies' compliance with the RFA that concludes: "The SBA annual reports indicated agencies' compliance with the RFA has varied widely…Some agencies…were repeatedly characterized as satisfying the RFA's requirements, while other agencies…were viewed by SBA as recalcitrant…Still other agencies' RFA compliance reportedly varied over time…or varied by subagency…"
June 1995	The third White House Conference on Small Business asks for specific provisions to strengthen the RFA by subjecting additional agencies, including the IRS, to the law; granting judicial review of agency compliance; and including small businesses in the rulemaking process.
Oct. 1995	Advocacy submits its report to Congress, *The Changing Burden of Regulation, Paperwork and Tax Compliance on Small Business*. Data in the report show that small firms with fewer than 20 employees pay 40 percent more in compliance costs than large businesses per dollar of sales; or, measured differently, 33 percent more than large businesses per employee.
March 1996	**The Small Business Regulatory Enforcement Fairness Act (SBREFA), is signed into law**, giving courts jurisdiction to review agency compliance with the RFA, requiring the Environmental Protection Agency and the Occupational Safety and Health Administration to convene small business advocacy review panels, and affirming and expanding the Chief Counsel for Advocacy's authority to file *amicus curiae* briefs in appeals brought by small entities from final agency actions.
1996-Present	Advocacy conducts training sessions for more than 2,000 trade association executives and federal officials.
Jan. 7, 1998	Advocacy files its first *amicus curiae* brief and the court remands the challenged rule to the agency on March 13, 1998.

For 15 years, the Chief Counsel reported rather graphically that compliance with the RFA was uneven throughout the government. This was confirmed by the General Accounting Office's (GAO) study in April 1994, cited in the chronology. Recognition was growing that some "teeth" needed to be added to the RFA. This would provide more incentive for agencies to comply with Advocacy's congressional mandate deemed so important to the national economy.

Enactment of the Small Business Regulatory Enforcement Fairness Act (SBREFA)

In March 1996, the Small Business Regulatory Enforcement Fairness Act (SBREFA) became law. SBREFA raised the stakes for regulatory agencies. Congress had finally been persuaded by 15 years of uneven compliance with the law, and by the repeated urging of the small business community, to authorize the courts to review agency compliance with the RFA. "Judicial review" was thought to be the incentive that was lacking in the original statute. SBREFA also reinforced the RFA requirement that agencies reach out to small entities in the development of regulatory proposals, subjecting this outreach to judicial review as well.

Very explicit outreach responsibilities were imposed on the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA). These two agencies are required to convene small business advocacy review panels that consult with small entities on the overall effectiveness and impacts of specific proposals.[5] This precedent-setting provision of the law institutionalizes outreach to small entities and ensures that these two agencies identify and consider effective alternatives that accomplish their public policy objectives. The Chief Counsel for Advocacy and the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) are statutory members of the panels and are mandated to partner with these agencies to consult with small entities on regulatory proposals. They report their findings, jointly with agency staff, to the head of the agency. Advocacy and OIRA have access—by act of Congress—to an agency's earliest deliberations that identify a problem, document the scope of the problem, analyze its various causes, and evaluate how best to address the problem without unnecessary harm to small business or the economy.

"Clearly, SBREFA provided much needed 'teeth' to the RFA by…allowing for judicial review of selected portions of the RFA. This is a powerful tool for the small business community and has empowered small business…to fight oppressive regulations effectively."—Laura Skaer, Northwest Mining Association

From a statutory perspective this overview brings us to today— four years after the passage of SBREFA and 20 years after enactment of the Regulatory Flexibility Act.

5. Specifically, panels must be convened whenever these two agencies believe they will be required to perform an initial regulatory flexibility analysis. See: 5 U.S.C. § 609 (b).

The balance of this report reviews:

RFA Compliance Now

- The value of outreach to small business—RFA mandates
- The role of economic and scientific data
- *Amicus curiae* authority
- The *significant* economic impact of RFA, as amended by SBREFA
- RFA Winners, Honorable Mentions and Agencies in Need of Improvement

The Future—What Lies Ahead

Conclusion

RFA Compliance Now

How SBREFA Has Changed the Dynamics of Regulatory Development

The RFA has meant different things to different agencies. Some have viewed it as merely a procedural law—a checklist or a legal hoop to jump through—compliance with which could easily be achieved if agencies just crossed the t's and dotted the i's. Some agencies did not view it as having mandated an analytical process to be customized to an agency's mission. Some failed to understand that RFA's mandates did not lend themselves to a "cookie cutter" approach, or that the RFA specifically was designed to eliminate a "one-size-fits-all" approach to regulation. Some chose to ignore the law's mandates altogether, at least initially. Most agencies found compliance with the RFA to be a difficult and useless exercise, in part because they were at the bottom of the learning curve on how to do the kind of impact analyses required by the RFA. They also resisted appropriate analyses because they believed the law gave special treatment and an unfair advantage to small business. Other agencies have taken substantial steps to comply with both the letter and spirit of the RFA.[6]

SBREFA, which has been in effect for four years, has started to change these dynamics. Advocacy is convinced that the impetus for the change comes from the amendment that allows the courts to review agency compliance with the RFA. This, in combination with the Chief Counsel's authority to file as *amicus curiae* in regulatory appeals, provides a powerful incentive for agencies to reduce the risk of having their rules judicially challenged in court and remanded for failure to comply with the RFA.

It appears that the threat of judicial review is making agencies acutely aware of the need to perform regulatory impact analyses. By performing regulatory analyses, even with incomplete data, some agencies have begun to recognize that early review of rules for potential small business impacts results in more informed decision-making. More agencies are beginning to provide more factual information, as required by the RFA, to justify their certifications that rules will not have a significant economic impact on a substantial number of small entities. Regulatory flexibility analyses, and the economic data that supports them, are also showing real improvement. At the same time, the OSHA and EPA small business advocacy review panels are clearly demonstrating the value of early consultation with small entities. Rules have been modified and compliance

Judicial Review

"One could say this litigation under the RFA has been a "learning experience" for the agency. Our efforts to comply with the Regulatory Flexibility Act, though well intentioned, have not always met with judicial favor. We recognize that there is room for improvement in our economic analyses, and I would like to describe the steps we are taking to make them better."—Testimony of Penelope Dalton, Assistant Administrator for Fisheries, National Marine Fisheries Service, before a subcommittee of the U.S. House of Representatives; April 29, 1999.

6. See Appendix J of the *Background Paper on the Office of Advocacy, 1994-2000*, at http://www.sba.gov/advo www.sba.gov/advo, for a list of court cases that address RFA issues.

costs reduced. The panels are providing concrete evidence that rulemaking that analyzes small entity impacts does not compromise public policy and results in more workable and reasonable rules.

"The concerns of the small business community are important to the CPSC. The Commission has made significant efforts to reach out to small businesses and consider the impact of our activities on them."—Thomas W. Murr, Jr., Deputy Executive Director, U.S. Consumer Product Safety Commission (CPSC).

These changes are the result of:

- small businesses challenging rules and requesting judicial review of agency compliance with the RFA; and
- Advocacy's first *amicus curiae* brief filed in a case that resulted in the remand of a rule to the regulatory agency.

It is safe to say that federal agencies today are finally beginning to do what they should have been doing since the RFA first became law in 1980: considering small business concerns as rules are being developed—not as an afterthought.

Pre-Proposal Consultation—The Major Change

One of the more significant changes that emerged just in the past year is the amount of consultation agencies have sought with Advocacy prior to publication of a rule for public comment. In FY 2000, the amount of pre-proposal activity in which Advocacy has participated has dramatically increased. Advocacy estimates that approximately 18 percent of the regulatory staff's time has been spent on pre-proposal work (an estimated 4,300 hours), exclusive of the staff time spent on SBREFA EPA and OSHA panels.[7]

"...[D]uring a recent DOT.....rulemaking, the Office of Advocacy played the leading role in persuading the agency to reverse their negative small business effect certification. By this action the entire nature of the rulemaking was changed to the benefit of small coach operators." —Norm Littler, United Motorcoach Association

An ever-increasing number of agencies are contacting Advocacy with questions about potential RFA problems and small business economic impact analyses.[8] This type of early consultation has led to the development of better rules, namely, rules that accomplish the agencies' public policy goals while avoiding undue burdens on small entities. When Advocacy has been successful in altering a proposal prior to publication, the need to submit comments for the public record has been eliminated. This shift to pre-proposal work is productive for agencies, for Advocacy, and most important, for small business. Time and again Advocacy has successfully identified weaknesses in agency analyses before publication. It has also demonstrated how to provide information that would be the most useful to the public in order to elicit informed submissions from the public during the comment period. This early attention to RFA compliance issues helps reduce the overall cost of regulatory development and the risk that a rule will be

7. Advocacy has instituted a tracking system to document time spent on pre-proposal work. This is one measure of work output since the work product of these consultations (memos, meetings, etc.) by law are not available for public disclosure.
8. In FY 2000, Advocacy worked with the following agencies on pre-proposal work: the Department of the Interior, the National Forest Service, the National Marine Fisheries Service, the Department of Labor, the Department of Transportation, the Department of Health and Human Services, the Food and Drug Administration, the Internal Revenue Service, the Securities and Exchange Commission, and the Office of Information and Regulatory Affairs.

judicially challenged. There is no question that a rule that goes through this process results in more informed public policy.

To illustrate:

- Advocacy worked with an agency in the **Department of Transportation** (DOT) on a rule affecting small business. This partnership resulted in the agency altering its conclusion that the rule would not significantly affect small entities. Instead, DOT made a commitment to analyze the possible economic impacts further.

- The **Forest Service** agreed to perform an initial regulatory flexibility analysis (IRFA), as required by the RFA, after Advocacy reviewed its draft proposal during early consultation and persuaded the agency that the rule would in fact have an impact on small commercial operations as well as on small communities.

- The **Minerals Management Service** dramatically improved the justification for its RFA certification so that the public was able to provide useful comments on the accuracy of the agency's determination.

These are just a few of the many ways in which Advocacy's work on agency compliance with the RFA is extremely beneficial—and cost effective—when done at the pre-proposal stage of regulatory development.

The Value of Outreach to Small Entities—RFA Mandates

When the RFA was enacted in 1980, Congress established procedures for agencies to follow to ensure that small entities would have the opportunity to participate in the rulemaking process.[9] These procedures included direct notification to affected entities and measures to reduce the cost or complexity of participation. Congress' clear intent was that small entities should be at the regulatory table and that the process should be made easy for them.

This mandate was also in response to the reality that large business has well-financed lobbyists with fine-tuned government networks through which they can work very effectively to influence public policy, sometimes to the detriment of other sectors in the economy. Special interests also have ready access to other vehicles through which to make their voices heard, such as government advisory committees, negotiated rulemaking, subsidized industry conferences, etc. Given this reality, complaints that suggested outreach to small business gave it an unfair advantage are unfounded. The mandates merely balance the scales.

9. 5 U.S.C. §609 (a)

With the SBREFA amendments Congress took the mandated outreach process one step further.

Small Business Advocacy Review Panels—The Outreach Process Mandated for EPA and OSHA

In 1996, SBREFA mandated that whenever EPA or OSHA finds that a regulatory proposal may have a significant economic impact on a substantial number of small entities, the agency is required to convene a panel and prepare a regulatory flexibility analysis. The review panel consists of representatives from the rulemaking agency, Advocacy, and the Office of Information and Regulatory Affairs within the Office of Management and Budget. The panel conducts its own outreach to small entities likely to be affected by the proposal, seeks their input on the proposed regulation, and prepares a report to either the EPA or OSHA with recommendations for reducing the potential impact of the rule on small businesses. The panel has 60 days in which to submit a report on its findings, which becomes part of the public rulemaking record. After the report is received, the agency may reconsider its proposal or modify it in response to the information received.

"Each of the 15 complete SBREFA panels has resulted in positive outcomes for the Agency and small businesses. In each case the Panel's report has included concrete recommendations to the Administrator for her to consider in the development of the subject rule."—Thomas E. Kelly, U.S. Environmental Protection Agency.

To date, work has been completed on 24 small business advocacy review panels—21 EPA panels and 3 OSHA panels (Table 1).

Because EPA has worked on more panels, it has been able to fine-tune the process to ensure that the right kinds of information and analyses are made available to the small entities to be consulted by its panels. EPA's performance has not always been consistent across the board, but on the whole its record surpasses other affected federal agencies.

To date, approximately 400 small entities have been consulted on a very diverse array of rules. The additional input from small entity representatives has spotlighted real-life consequences of proposals under consideration. In nearly every instance to date, information provided by small entities, in combination with other data, has proven invaluable in establishing a reality check for these agencies, namely, what the real impact of the regulation is likely to be and the actual compliance costs small entities will have to bear. Regulations that have emerged from the panel process have been changed in response to the concerns of small business and are less burdensome than the regulations initially considered by the agency. In one instance, a regulation was withdrawn entirely because the data clearly demonstrated that there was no need for national regulation, saving small businesses approximately $103 million annually.[10] All of these

10. In July 1999, EPA decided to withdraw the industrial laundries water pollution regulation. Based on the EPA's economic analysis, Advocacy estimates the savings to be $103 million annually. See press release on Advocacy's home page at www.sba.gov/advo.

Table 1. SBREFA Panels through Fiscal Year 2000

Rule Subject	Date Convened	Report Completed	NPRM
Environmental Protection Agency Panels			
Non-Road Diesel Engines	03/25/97	05/23/97	09/24/97
Industrial Laundries Effluent Guideline	06/06/97	08/08/97	12/12/97
Stormwater Phase 2	06/19/97	08/07/97	01/09/98
Transport 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
Underground Injection Control Class V Wells	02/17/98	04/17/98	07/29/98
Ground Water	04/10/98	06/09/98	05/10/00
Federal Implementation Plan for Regional Nitrogen Oxides 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	11/02/99
Long Term 1 Enhanced Surface Water Treatment	08/21/98	10/19/98	04/10/00
Filter Backwash Recycling	08/21/98	10/19/98	04/10/00
Light Duty Vehicles/Light Duty Trucks Emissions and Sulfur in Gas	08/27/99	10/26/98	05/13/99
Arsenic in Drinking Water	3/30/99	06/04/99	06/22/00
Recreational Marine Engines	06/07/99	08/27/99	In process
LDV/LDT Emissions and Sulfur In Gas	08/27/98	10/26/98	05/13/99
Diesel Fuel Sulfur Control Requirements	11/12/99	03/24/00	06/02/00
Lead Renovation and Remodeling Rule	11/23/99	03/03/00	In process
Metals Products and Machinery	12/09/99	03/03/00	In process
Concentrated Animal Feedlots	12/16/99	04/07/00	In process
Reinforced Plastics Composites	04/06/00	06/02/00	In process
Stage 2 Disinfectant Byproducts	04/25/00	06/23/00	In process
Occupational Safety and Health Administration Panels			
Tuberculosis	09/10/96	11/12/96	10/17/97
Safety and Health Program Rule	10/20/98	12/19/98	In process
Ergonomics Program Standard	03/02/99	04/30/99	11/23/99

Note: NPRM = Notice of Proposed Rulemaking

significant changes have resulted in rules that are less burdensome on small entities *without compromising the public policy objectives of the agencies.*

"I was a small entity representative for industry in the SBREFA processes and worked closely with [Advocacy]...to reduce the impact of [EPA] regulations. Together we have established precedent-setting regulations and procedures that will likely save the regulated community several hundred million dollars annually."—Jack Waggener, URS Corporation.

Although work on the panels has been productive, it has also been labor-intensive. For the seven panels completed in FY 2000, Advocacy alone spent an average of 700 hours per panel—for a total of 4,900 hours.[11] While time-consuming for Advocacy (and OIRA), once the analytical process becomes part of the agency's regulatory culture, agencies subject to the SBREFA panel process should not experience any additional burden over and above what they are already required to do under the Administrative Procedure Act (APA). Advocacy has consistently maintained that the analysis required by the RFA in preparation for a SBREFA panel is not an additional burden. Rather, it is exactly the kind of analysis an agency is already mandated to do by the APA. What the RFA added to the process was a congressional mandate to consider explicitly the impacts on small business, which agencies should have been doing all along, in order to avoid harming competition unnecessarily.

"[F]ollowing the small business panel session on ergonomics, the Office of Advocacy brought to light some major deficiencies with OSHA's draft ergonomics proposal and the difficulty industry will have to comply with the rule."—Don E. Gaertner, American Foundry Society.

Any additional work that may be needed to complete the 60-day panel process is offset by time saved at the other end of the regulatory process. When problems are resolved prior to publication, objections from the public are reduced and less time must be spent crafting responses. All of the rules reviewed by EPA and OSHA SBREFA panels that have now been finalized were modified significantly to mitigate unnecessary and unproductive burdens on small business and to eliminate unworkable provisions. Even OSHA's controversial ergonomics final rule, though much criticized by small business, was changed dramatically as a result of the input from small business during the SBREFA panel process. Without that crucial step in the rule's development, the pre-panel draft of the rule would most likely have become the proposed rule, costing small businesses even more in compliance costs. SBREFA panels continue to be an important mandate of the RFA that ensures small business a formal seat at the regulatory table, where their input can and does make a real difference.

Advocacy's Outreach to Small Entities

In addition to its work on panels, Advocacy hosts roundtable discussions to gather information on current trends and regulatory impacts from small businesses themselves. When monitoring agency compliance with the RFA, it is useful for Advocacy to understand the impact of proposed regulations on specific industries. Frequently, the necessary historical data on those industries does not exist. In order to develop some

11. These hours are just the hours spent by Advocacy staff on the 60-day panel process and are in addition to the 4,300 hours, referenced earlier, spent on pre-proposal work with agencies.

knowledge about current industry structure, etc., these industry-specific roundtable meetings have been convened by Advocacy to discuss pending issues on an ad hoc basis with small business representatives. Representatives from relevant regulatory agencies and congressional committee staff have also been invited to participate. The meetings have uniformly been viewed as helpful in identifying and raising awareness of small business issues.

"Through the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, your office has provided small business a stronger voice in the federal regulatory process."—Don E. Gaertner, American Foundry Society

The Role of Economic and Scientific Data

Not all policymakers understand or accept the important role played by small business in maintaining competition. Too often they are familiar only with the literature produced by business schools and research addressing big business issues. The adverse long-term impacts of industrial concentration on price, innovation, and choice are not readily understood. This lack of understanding complicates the task of persuading agencies—often focused on other important but more narrow policy missions—that they are also responsible for the larger national policy objective of preserving competition. More specifically, this means "do no undue harm to small business."

It is a well-established economic axiom that "information rationalizes markets." Information also rationalizes public policy. This is one of the underlying reasons that Congress mandated that agencies reach out to small businesses and involve them in the process. As noted earlier, small business input on SBREFA panels has been a major influencing factor in fashioning more workable regulations.

The information obtained from these small businesses themselves, though vital, is generally anecdotal. The challenge before agencies and the Office of Advocacy is to develop statistically sound data (both economic and scientific) that document the existence, scope and causes of a problem. Additional important information assesses who the responsible parties are and the extent of their contribution to a problem. This analysis leads to an intelligent determination of how the causes can be remedied by regulation. Much of Advocacy's time in connection with SBREFA panels is spent reviewing agency data and having it validated or challenged by independently obtained data.

The importance of data to the regulatory process and rational decision-making cannot be overemphasized. It was data that persuaded EPA to drop an industrial laundries water pollution regulation that saved small businesses approximately $103 million annually. The data showed there was no need for a national rule. It was data that convinced OSHA that its compliance cost estimates were too low for its ergonomics rule.[12]

12. As an aside, Advocacy's cost estimates for the ergonomics rule were used, but misquoted, in the November 8, 2000, episode of the TV program *West Wing*.

Advocacy anticipates that one of the benefits that will emerge from early consultation with agencies on RFA issues will be increased awareness of what agencies do not know—but should know—about the industries they are trying to regulate. This will help agencies understand how the regulatory process aids in eliciting relevant information from the public. Further, agencies unwittingly fail to use, or chose to ignore, readily available in-house information (e.g., company data submitted to obtain licenses, etc.).

For now, Advocacy issues task order contracts to researchers who are hired on a task-by-task basis to analyze data in connection with specific rules. This increases Advocacy's flexibility. It avoids the need to hire full-time staff with narrow specialties to perform tasks that can be more readily obtained at less cost to the taxpayer through a contractor for the short period of time needed to analyze a rule.[13]

Partnership with the Office of Information and Regulatory Affairs (OIRA)

On January 11, 1995, the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) and Advocacy signed an "Exchange of Letters" outlining how both agencies would work together on regulatory issues. In those letters Advocacy agreed to contact OIRA whenever it had concerns about an agency's compliance with the RFA. OIRA in turn agreed that it would consult with Advocacy when it was not able to resolve RFA issues with an agency.

The SBREFA panel process brought Advocacy and OIRA even closer together, and from this relationship a mutual respect has developed. OIRA is also responsible for ensuring agency compliance with Executive Order 12866 and the Paperwork Reduction Act, both of which concern Advocacy from a small business perspective.[14] Increasingly, OIRA is sharing agency rulemaking drafts with Advocacy in order to obtain initial comments on an agency's RFA compliance as part of the EO review. This early access to important agency information enables Advocacy to comment at a vital stage of the rule's development and have an impact on its final design.

Prior to promulgation of a final rule, Advocacy often participates in meetings and discussions with both OIRA and the relevant regulatory agency, in order to advocate for crucial RFA-mandated changes on behalf of small business. This important working relationship with OMB at all stages of a rule's development has assisted the Office of Advocacy in monitoring agency compliance with the RFA more closely. This new and improved working relationship has been mutually beneficial.

13. The scope of this work is, however, determined by the amount of funding available.
14. Executive Order No.12866, 58 Fed. Reg. 51,735 (1993); The Paperwork Reduction Act, 44 U.S.C. 3501 *et seq*.

Amicus Curiae Authority

Section 612 of the RFA vests in the Chief Counsel for Advocacy the authority to appear as *amicus curiae* (i.e., "friend of the court") in any court action to review a rule. Specifically, the Chief Counsel is authorized to present views with respect to compliance with the RFA, the adequacy of a rulemaking record pertaining to small entities, and the effect of rules on small entities. Under this section of the RFA, courts are bound to grant the *amicus curiae* application of the Chief Counsel.

This section of the RFA existed prior to SBREFA, albeit in a slightly different form. Prior to the 1996 SBREFA amendments, some argued that the section limited the Chief Counsel's authority only to reviewing the effects of a rule on small entities. In this context, the courts were bound to grant the *amicus curiae* application of the Chief Counsel. However, this very general authority did not explicitly allow the Chief Counsel to raise RFA issues because there was no judicial review of RFA actions prior to SBREFA. Consequently, the Chief Counsel had to use creative means to enter his appearance in court actions if he wanted to challenge a regulation based on an agency's failure to comply with the RFA. For instance, in 1994, the Office of Advocacy prepared an *amicus curiae* brief in the case of *Time Warner Entertainment Company v. FCC*, 56 F.3d 151 (D.C. Cir. 1995), *cert. denied*, 516 US 112 (1996). The Chief Counsel argued, among other things, that noncompliance with the RFA was arbitrary and capricious under the Administrative Procedure Act. After last-minute negotiations, the FCC agreed to alter its policy and Advocacy withdrew its notice of intent to file.

"It is our opinion that the Office of Advocacy's interventions into our case and the subsequently filed amicus brief in support of our position challenging the regulations clarified the issues for resolution by the court. The Office of Advocacy's brief was very persuasive to the court's favorable interpretation of the RFA and SBREFA in accordance with congressional intent."—Laura Skaer, Northwest Mining Association.

As the *Time Warner* case demonstrates, the threat of filing a brief in court is sometimes sufficient to persuade an agency to change its course. For instance, in the case of *Grand Canyon Air Tour Coalition v. FAA*, 154 F.3d 455 (D.C. Cir. 1998), Advocacy withdrew its notice of intent to file a brief in exchange for an agreement with the U.S. Department of Transportation (DOT). The agreement required DOT to submit to the court a statement detailing new data regarding the number of aircraft subject to the regulation. Further, DOT was to include in its communication to the court a statement that the agency erroneously certified that the final rule would not have a significant economic impact on a substantial number of small entities.

In *Southern Offshore Fishing Association v. Daley*, 995 F. Supp. 1411 (M.D. Fla. 1998), Advocacy withdrew its notice of intent to file after it was able to obtain an agreement from the Department of Justice (DOJ) that the proper standard of review in

RFA cases is the "arbitrary and capricious" standard. This acknowledgment from DOJ was significant—not only because it conceded the use of the appropriate standard, but also because it implicitly accepted Advocacy's authority to file *amicus* briefs. This was an important concession, as DOJ had always objected to Advocacy's right to file such briefs in the past.

Advocacy has filed one *amicus curiae* brief since passage of SBREFA. *Northwest Mining Association v. Babbitt,* 5 F. Supp. 2d (D.D.C. 1998), involved a hardrock mining rule with a number of major defects. Advocacy argued that major new costly requirements were being introduced for the first time after a 6-year delay in issuing a final rule, and the agency's analysis was confusing and inadequate. The court chose to focus on the fact that the agency failed to comply with the definition of a small entity as defined in the RFA and the Small Business Act. Primarily because of Advocacy's arguments, the rule was remanded to the agency.

Advocacy uses its *amicus curiae* authority judiciously. Since Advocacy is not a litigation office, the time needed for writing a brief can present a strain on the office's resources. Therefore, in assessing whether to file a brief, Advocacy has established certain criteria. Two of the main criteria are whether the office can make a difference by getting involved and whether small business views will be adequately represented by others. The second criterion is derived from the fact that courts will not generally accept duplicative arguments made by *amicus curiae.*

The Significant Economic Impact of the RFA, as Amended by SBREFA

Given the uneven performance by agencies over the last 20 years, legitimate questions may be posed about the RFA. How effective has the RFA been? Has it been a total failure? What measures should be used to gauge the law's effectiveness? These questions need to be answered, if for no other reason than to overcome agency skepticism about the true meaning of the law.

For the past three fiscal years Advocacy has measured the difference between the compliance costs of an original regulatory proposal and those associated with the rule that ultimately emerges from the regulatory process. The difference between these costs measures the extent to which regulatory impact analyses (compliance with the RFA) altered the policymakers' views of how best to solve a problem. This measurement is termed "regulatory savings" (Table 2).

Table 2. Regulatory Savings

Fiscal Year	(1) One-Time Savings	(2) Annual Savings	(3) Cumulative Annual Total	Total (1) plus (3)
FY 1998	$-0	$3.2 billion	$9.6 billion (3 years)	$9.6 billion
FY 1999	$ 3.0 billion	$2.2 billion	$4.4 billion (2 years)	$7.4 billion
FY2000	$3.2 billion	$ .4 billion	$.4 billion	$3.6 billion
TOTAL:	$6.2 billion	$5.8 billion	$14.4 billion	**$20.6 billion three-year total**

Notes: See Appendix B for more information about the regulations that generated these savings. Some savings to small businesses are a one-time savings of costs avoided in one year (1). Others are saved by small businesses every year (2). The cumulative annual total in column (3) represents the annual savings times the number of years in which those savings have occurred, up to FY 2000.

While the three-year total of $20.6 billion in regulatory savings does not directly deposit any monies into the coffers of small business, the savings do represent monies small business did not have to expend on compliance with regulations. These figures dramatically highlight that compliance with the RFA does have a positive impact and does avoid unnecessary costs for small business. Agencies are to be applauded for adjusting their proposals when sound analyses dictate such an outcome. On the other hand, the figures also demonstrate that agencies need to do more analyses in advance of proposing regulations—which after all is the intent of the RFA.

Interestingly, the cumulative three-year total represents a return of between $1144 and $1373 for every dollar spent on Advocacy's total budget for the past three years, assuming that Advocacy's budget (including salaries, expenses and research funds) is between $5 and $6 million per year.[15]

The RFA Winners, Honorable Mentions, and Agencies in Need of Improvement

In the preface of this report, Advocacy noted that there has been significant turnover in the policy decision-makers within the federal government. In addition, some agencies promulgate more rules than do others; some have a spate of rules in one year, but none

15. Advocacy's budget and staffing are not separate items in the SBA's budget. These figures are therefore estimates.

in another year. These factors partially explain why compliance with the RFA by agencies and some sub-agencies of major departments has been uneven over the years. Until SBREFA, there was no real incentive to institutionalize the analytical process mandated by the RFA.

Despite SBREFA, uneven compliance exists today, although Advocacy perceives some improvements in agency efforts to comply with the law. Some agencies fail consistently to provide factual bases for their certifications that rules will not have a significant impact on a substantial number of small businesses. Others fail miserably in analyzing the impact of rules on small business, or fail to make their analyses transparent, thus frustrating the public's ability to assess the validity of the analyses or to pinpoint flaws in agency reasoning. Still others use boilerplate language either in certifications or in their analyses. Too many agencies still do not consider small business impacts as they are developing rules and address the issue only after the fact. Some agencies are learning the hard way—after court challenges—that there is a better way to develop rules. Some agencies are learning by observation. They watch what happens to other agencies that ignore the RFA. Agencies on the top of the learning curve quickly grasp how proper analyses can help them develop smarter rules.

In previous reports, Advocacy has discussed in some detail the contents of communications submitted for the record in various rulemakings. This year, that discussion is contained in Appendix B. The information contained therein provides a comprehensive overview of the diverse agencies and issues with which Advocacy has dealt in the past year. In reviewing this appendix it is important to appreciate that it contains information only on documents that are a matter of public record and does not contain any of the information or work product generated during interagency nonpublic pre-proposal discussions.

This year, in light of the RFA's 20th anniversary, Advocacy thought it appropriate to recognize those agencies that have made the most progress (Winners), agencies that have made some progress worth noting (Honorable Mentions) and those agencies whose performance needs significant improvement.

The following criteria were used to select agencies for recognition:

- Anticipating RFA problems and seeking guidance;
- Good faith outreach to small business;

- Adequate factual information to substantiate certifications;
- Well-documented regulatory flexibility analyses;
- Factual presentation of data on the structure and economics of the industry being regulated;
- Good-faith efforts to elicit information during the rulemaking process to supplement agency data;
- Compliance with the Small Business Act's and the RFA's size standards and the process for seeking exceptions;
- Consideration and evaluation of truly meaningful alternatives—not just alternatives that would never be seriously considered;
- Meaningful responses to Advocacy's critiques of regulatory proposals.

The Office of Science and Technology—EPA. The Office of Science and Technology is a division within the Environmental Protection Agency. This division has shown exemplary compliance with the objectives of the RFA during FY 2000. Its data and analyses have been extremely comprehensive, thus establishing a high level of credibility in the work of the staff. Its analytical work should serve as a model for the rest of EPA. The Office of Science and Technology has shown the ability to work effectively with the Office of Advocacy and industry during the promulgation of its rules. This relationship was instrumental in assuring significant cost savings on two rules: the metals products and machinery rule (panel completed in March 2000 and rule proposed in December 2000) and the transportation equipment cleaning rule (rule completed in August 2000). As a result of the cost savings generated by the two rules, Advocacy expects annual savings in excess of $100 million.

The Center for Food Safety and Applied Nutrition—HHS. The Center for Food Safety and Applied Nutrition (CFSAN), a division within the Department of Health and Human Services, is lauded for its efforts to help small entities. CFSAN has worked with Advocacy by offering briefings on upcoming regulations that will affect small entities before the regulations are even proposed. CFSAN seems to have made an institutional adjustment and a conscious decision to analyze thoroughly the impact of its regulations on small entities, thereby mitigating adverse impacts where possible. This institutional change came about after several harsh comments submitted earlier by Advocacy criticizing CFSAN's analyses and its failure to comply with the RFA. Officials from CFSAN have stated that it is more productive to work with Advocacy in

the earliest stages of rule promulgation than against Advocacy after a negative comment has been received. It is Advocacy's hope that CFSAN will maintain these practices when issuing new regulations on dietary supplements—regulations that contained RFA compliance problems in the past.

The Employee Benefits Office—Treasury Department. The Employee Benefits Office of the Treasury Department has made a special effort to respond to the small business community. During the last year, Advocacy has worked with the Employee Benefits Office and Treasury in an effort to resolve two major issues: more flexibility for small business 401(k) plans and comparability testing for defined contribution plans and benefits. The office has made an effort over the last five years to work with small business to simplify small business pension plans and increase benefits to reflect real retirement needs. Ultimately the efforts of the Employee Benefits Office have increased pension participation.

Securities and Exchange Commission. The Securities and Exchange Commission (SEC) has always maintained a positive relationship with the Office of Advocacy. The two agencies have long worked closely at the pre-proposal stage (and generally) to assure that SEC's policies remain sensitive to small business concerns. The SEC also is diligent in complying with RFA's size standards requirements and arguably has the best record of adhering to the statutory process for obtaining exceptions. In addition, the SEC can be commended for various efforts to reach out and include small businesses in its regulatory processes, including its successful Government Business Forum on Small Business Capital Formation. Information gleaned at this forum has had a direct impact on SEC regulations and policies.

The RFA Honorable Mentions

Two agencies have made noteworthy progress and deserve recognition for their efforts, even though more needs to be done to make them "winners."

Internal Revenue Service. The SBREFA extended the RFA to IRS interpretive rules that impose recordkeeping requirements. IRS has interpreted this provision narrowly and has certified rules that would impose de facto recordkeeping burdens. By the same token, it has on other occasions performed regulatory flexibility analyses when a rule explicitly imposed a recordkeeping burden. Advocacy is of the view that the IRS should be more sensitive to de facto burdens and perform more analyses. The Department of the Treasury and the IRS have made an informal effort to reach out on

regulations where it can be ascertained that a high-visibility problem exists for small businesses. In areas involving controversial definitions (such as worker classifications), cash versus accrual accounting, employment reporting, tip reporting, capitalization rules, and other industry-specific problem areas, the IRS has made a significant effort to appreciate small business concerns. The IRS and Treasury have become more amenable to gathering small business input before promulgating regulations. Such an informal effort is an encouraging sign, even if the IRS and Treasury continue to resist following the formal requirements of the RFA and SBREFA (see Appendix B).

National Marine Fisheries Service. Although Advocacy recognizes that the National Marine Fisheries Service (NMFS) still has work to do, it would be unfair not to recognize the efforts that NMFS has made to comply with the spirit of the RFA. After the passage of SBREFA, several NMFS regulations were challenged for failure to comply with the requirements of the RFA. In response to the judicial review provisions in SBREFA, NMFS began to work with Advocacy to improve its RFA compliance. By working with Advocacy on matters of concern, NMFS has addressed issues and, in some instances, like the regulations concerning "spotter planes" and the Florida Keys sanctuary, has avoided judicial review or overcome the court challenge

Noteworthy is the decision to make institutional changes in the manner in which they approached the RFA. Whereas they initially had standards to determine "significant" and "substantial," those standards were abandoned in an effort to encourage their regulators to perform an economic analysis, as opposed to simply certifying the rule and using the standards to justify the certification. NMFS consulted with Advocacy in developing the guidelines and also published them for public comment. NMFS has distributed the guidelines to all of their offices and is also providing training sessions for their regulators. NMFS should also be lauded for hiring an economist and an attorney specifically to work on RFA issues and to be a point person for their regulators in terms of RFA guidance.

In addition, NMFS has made significant attempts to increase their outreach to small entities. In addition to hiring an ombudsman to address small entity concerns, NMFS has made a concerted effort to send representatives to Advocacy roundtables. At the roundtables, NMFS listens to the concerns of the industry, explains the basis for some of its actions, and attempts to clarify misunderstandings. For example, at one roundtable, NMFS learned that some of the regional personnel would not provide fishers

with information about quotas if the matter was the subject of litigation. NMFS immediately addressed the problem by instructing the regional staff to provide the information and explaining which types of information can be released when a particular fishery may be the subject of litigation. While the relationship between the industry and NMFS may be somewhat strained, it is hoped that continued open exchange of information and institutional changes will improve that relationship.

Agencies in Need of Improvement

Some agencies exhibit compliance problems in some or all aspects of the RFA. Advocacy has tried to work with these agencies; has submitted public comments that were very explicit about the agencies' RFA deficiencies; but the agencies still need to apply the requirements of the RFA with greater consistency.

Having said this, Advocacy nevertheless wishes to extend an invitation to these agencies to develop a working relationship that will benefit the regulatory process, help small business, and produce smarter regulations. It would be Advocacy's goal to be able to characterize them as "winners" in next year's report.

The Federal Communications Commission. The Federal Communications Commission (FCC) is notorious for its poor compliance with the RFA. Although the FCC frequently provides detailed insight into the purposes and rationale underlying a rule, it offers only cursory discussion of a rule's impact on small business. The FCC's regulatory flexibility analyses are invariably cut-and-paste, offer no real insight, and are entirely divorced from the "substantive" portions of the rulemaking. The FCC also violates requirements governing size standards for small businesses established under the Small Business Act. The agency has established a general pattern of changing size standards as it sees fit, often approaching SBA to seek an exception only after it has adopted a new size standard. Advocacy recognizes the limited discretion FCC staff is allowed to exercise within an agency where decisions are made by a collegial body. This does not excuse the commission itself, however, since it has been made well aware of its legal responsibilities under the RFA. Although there have been several training sessions for commission staff, including staff of the commissioners, Advocacy sees little evidence that change is occurring to improve compliance.

The Health Care Financing Administration—HHS. The Health Care Financing Administration (HCFA) is a division within the Department of Health and Human Services. Despite HCFA's challenging congressional mandate to implement major

Medicare reforms within short statutory deadlines, Advocacy believes that it could do a better job of considering less burdensome regulatory alternatives that still meet statutory requirements and of following administrative procedures that require public notice and comment. Also, many health care providers have expressed great frustration with HCFA and some of the practices of its regional carriers, in particular. It is hoped that HCFA will rid itself of this negative public perception by looking more closely at regulatory alternatives and by forcing its regional carriers to apply HCFA's guidelines with significantly greater consistency.

Advocacy has heard many complaints, past and present, regarding the inconsistency with which HCFA's regional carriers apply HCFA's guidance in processing provider claims. Many small businesses have complained that the regional carriers abuse their discretion, delay claims unnecessarily and otherwise process claims in an arbitrary fashion, with differing processing practices across the country. HCFA should make every attempt to reign in abusive and inefficient carriers.

In the past, HCFA had developed the practice of publishing rules as direct and interim final rules. This was the case in several major regulations like the ones for surety bonds for home health agencies, the interim payment system for home health agencies, and inherent reasonableness. Doing so allowed the agency to bypass notice and comment procedures required by the Administrative Procedure Act. The agency also requested expedited OMB review of paperwork requirements in a situation Advocacy believed did not warrant such a procedure. In this particular case, Advocacy had already submitted comments criticizing a similar action by the agency in an analogous situation the previous year. In both situations—issuing direct final rules and requesting expedited OMB review—affected entities are precluded from commenting on the potential effects of the rule.

Finally, on the issue of alternatives, Advocacy continues to work with the agency to devise less burdensome alternatives in its regulations. For instance, Advocacy continues to urge the agency to provide an analysis and regulatory alternatives for its rule that deals, in part, with the length of time patients can be restrained in a medical facility. A court has also ruled that this analysis is required.

HCFA has made progress in its RFA compliance efforts recently, and is beginning to consult Advocacy early on some controversial regulations.

The Food and Nutrition Service—USDA. The Food and Nutrition Service (FNS) is a division within the U.S. Department of Agriculture. At least twice in FY 2000, FNS certified that its regulations would not have a significant economic impact on a substantial number of small entities. However, there was no factual basis for the certifications. FNS does not discuss the number of small entities affected by the rule—an RFA requirement for determining whether a substantial number of small entities are, or are not, affected. Moreover, neither rule adequately explained why the impact of the rule would not be significant.

The Food Safety and Inspection Service—USDA. The Food Safety and Inspection Service (FSIS) is a division within the U.S. Department of Agriculture. It issued "policy changes" at least twice in 1999 affecting thousands of small entities.[16] Despite the impact of both policy changes, the agency failed to do any economic analyses. In the opinion of the Office of Advocacy, this violated the Administrative Procedure Act, as FSIS failed to publish the changes as proposed rules. When rules are not published for public notice and comment they are not subject to the requirements of the RFA—resulting in further negative impacts on small business. On a positive note, FSIS contacted Advocacy in September 2000, requesting a tailored briefing on how to comply with the RFA. Advocacy conducted this briefing for about 25 FSIS and USDA staff, with great emphasis on the definition of a small entity for purposes of the RFA. Advocacy hopes the briefing will serve to make FSIS more sensitive to small business issues in the future.

16. These issues were inadvertently omitted from Advocacy's FY 1999 report, but the agency has yet to address the problems satisfactorily, in Advocacy's view. Therefore, they are mentioned in this FY 2000 report.

The Future

Unresolved Issues on Which Reasonable People May Differ

The RFA Imposes an Analytical Process on Regulatory Development—Not Just a Procedure

As stated earlier, some agencies treat the RFA as though it is solely a procedural hurdle rather than an analytical process they must follow. Often these agencies craft their regulations and then devise analyses to justify the agencies' policies. Advocacy is of the view that the RFA requires agencies to make the analyses an integral part of regulatory development—while the rule is being drafted. Shortcuts frequently lead to folly, as illustrated by the following example in which the General Accounting Office (GAO) sanctioned a rule over Advocacy's objections, despite concluding that the data used in the rule were fatally flawed.

The Food and Drug Administration (FDA) proposed a rule to regulate dietary supplements containing herbal ephedra (an herb that has properties similar to the chemical pseudoephedrine which is used in over-the-counter cold medications). In proposing the regulation, the agency cited thousands of adverse event reports (AERs) supposedly linked to the use of products containing herbal ephedra. The new dosage and labeling requirements in the proposal would mean that the product could no longer be marketed for weight loss. In reality the agency failed to provide a factual basis to support the need for the regulation. Further investigation by Advocacy and the industry revealed that hardly any of the AERs established a causal connection to the use of ephedra. If no causal connection is established, there is no basis for the rule.

The GAO was asked by Congress to examine the scientific basis for FDA's proposed rule and examine FDA's adherence to the regulatory analysis requirements for federal rulemaking. In its report, *Dietary Supplements: Uncertainties in Analyses Underlying FDA's Proposed Rule on Ephedrine Alkaloids* (July 1999), the GAO found serious deficiencies with the data and studies used to support the regulation. The GAO stated that FDA did not establish a causal link between the ingestion of the products and the occurrence of adverse events for either its proposed dosing level or duration of use. FDA's benefits analysis could not be duplicated because it failed to identify which "serious" adverse event reports it had relied upon. The GAO also stated that FDA had no internal guidance on the use of AERs for rulemaking related to dietary supplements, and the AERs were used differently in this proposed rule than in prior rulemaking.

Finally, the GAO indicated that the agency did not always disclose why certain key assumptions were made, the degree of uncertainty involved in those assumptions, or the fact that alternative assumptions would have had a dramatic effect on the agency's estimate of the benefits.

After reaching these conclusions, the GAO inexplicably found that FDA met the requirements of the RFA. This conclusion, of course, is counterintuitive. How did the GAO reach this conclusion? The obvious answer: by treating the RFA as a mere procedural statute. According to the GAO, FDA jumped through all of the necessary RFA "hoops," so the fact that the data and analysis relied on by the FDA were flawed was irrelevant. The GAO explained that although the FDA acknowledged that the rule would affect small businesses, FDA adequately described the affected small businesses and discussed alternatives in compliance with the RFA. Perhaps the FDA concluded that since the RFA does not specifically require accurate data, then the RFA requirements were technically met—a preposterous theory.

In Advocacy's view GAO's interpretation of the RFA's requirements is unquestionably erroneous and deviates completely from the purpose and intent of the RFA. GAO has issued similarly flawed reports in recent years that trend toward the agency treating the RFA as a procedural statute. Advocacy has serious concerns with GAO's conclusions about RFA compliance. In the future, GAO and other agencies must understand that the RFA imposes analytical as well as procedural requirements.

What Did Congress Mean by "Significant" and "Substantial"?

There has been much discussion over the years as to the need to define "significant" and "substantial" with some specificity. GAO is in the forefront of the effort to get specificity. Federal agencies believe that the undefined terms are too vague even though the nation has been well served by laws such as the Federal Trade Commission Act that outlaws "unfair competition" without defining "unfair competition." It is like pornography—one knows it when one sees it.

When the RFA was adopted, Congress expressly left the terms undefined so that agencies would evaluate and analyze the impact of each regulation in the context of the industries being regulated and the types of requirements being imposed by the regulation. In other words, each regulation was to be treated as if it were the equivalent of a snowflake—each different in its own way. By not defining the terms, agencies could determine whether something was "significant" or "substantial" based on the unique

requirements of the regulation and in the context of an ever-changing economy and changing industry structures.

In the legislative history of the RFA, Congress discussed some of the measures an agency might use, but again, ultimately decided that definitive measures should not be included in the statute. For instance, legislative history says that the term "substantial" is intended to mean a substantial number of entities within a particular economic or other activity.[17] The history also states that agencies would not be required "to find that an overwhelming percentage [more than half] of small [entities] would be affected before requiring an IRFA."[18]

As for "significant," Congress said, "the term 'significant economic impact' is, of necessity, not an exact standard. Because of the diversity of both the community of small entities and of rules themselves, any more precise definition is virtually impossible and may be counterproductive."[19] Moreover, Congress identified several examples of "significant": a rule that provides a strong disincentive to seek capital;[20] having impacts greater than the $500 fine imposed for noncompliance;[21] new capital requirements beyond the reach of the entity;[22] any impact less cost-efficient than another reasonable regulatory alternative;[23] and any impact where the adverse cost impact is greater than the value of the regulatory good.

Some agencies like the Marine Fisheries Service and the Department of Health and Human Services at some point established their own definitions for these terms. The latter has said that a rule is not significant if it would not reduce revenues or raise costs of any class of affected entities by more than three to five percent within five years.

Advocacy believes it would be a daunting task to construct a specific definition or even a set of definitions that would apply to all industries for all times in an economy that is so diverse and in which the composition and cost and profit structures are constantly changing. No one can forecast how the economy will change, what industries will grow, what problems will emerge. Lack of specificity reserves the options for public policymakers to know "significant" and "substantial" when they see it and justify their analysis in the context of the economy as it exists when a rule is being developed.

17. 126 *Cong. Rec.* S10938 (1980), (Section-by-Section Analysis of the Regulatory Flexibility Act).
18. 126 *Cong. Rec.* at S10941 and 10942.
19. 126 *Cong. Rec.* at S10942.
20. 126 *Cong. Rec.* at S10938.
21. 126 *Cong. Rec.* at H24578.
22. 126 *Cong. Rec.* at H24593.
23. 126 *Cong. Rec.* at H24595.

For these reasons, Advocacy is likely to discourage future attempts to construct a statutory or regulatory definition for these terms.

Other Suggested Amendments to the RFA

Other suggested amendments to the RFA would require agencies to weigh the indirect cost effects of regulation, and to close the loophole that allows agencies to bypass the requirements of the RFA by publishing interim or direct final rules.

The future effectiveness of the RFA may be helped or hindered based on future amendments to the law.

Budgetary Needs of Advocacy

Advocacy does not have a line item in SBA's budget for a budget that includes salaries and expenses. Therefore, its budget and staffing are driven by SBA's support and budget constraints. The office can do as much or as little as the budget allows.

Over the years, Advocacy's personnel ceiling has declined dramatically, despite increases in the statutory responsibilities undertaken by the office. Staff productivity has increased dramatically, due largely to an increase in the staff's expertise, as well as new working relationships with agencies and the regulated industries. Thus far, the staff has been able to avoid major omissions in its review of regulations, but the increase in resources being devoted to pre-proposal activity (over and above the SBREFA panel process) is stretching Advocacy's resources. There has been some congressional interest in giving Advocacy a separate line item in the SBA's budget for its entire operation but no action has been taken thus far.[24]

Possible Legislative Proposals

RFA Amendments. Since SBREFA became law in 1996, some observers have suggested further amendments to the RFA. For example, legislation introduced in the 106th Congress would have extended the SBREFA small business advocacy review panel requirements to the IRS and the Department of Labor's Mine Safety and Health Administration. Advocacy has not taken a position as to whether the addition of other agencies would be advisable, but does acknowledge that the process has worked well for the agencies that are currently covered by the panel requirements. Also, Advocacy encourages agencies to convene SBREFA-like panels on their own initiative since they are obligated under the RFA to reach out to small businesses in the development of regulations. Agency compliance with the outreach provisions of the RFA is subject to judicial review and instituting SBREFA-like panels could serve to satisfy an agency's obligations under the law.

24. See Appendix "P" to the *Background Paper on the Office of Advocacy, 1994-2000* at www.sba.gov/advo.

Advocacy's Independence. Two proposals were introduced that were designed to increase Advocacy's independence. One proposal would have established a separate budget line item for the office and defined the conditions under which the Chief Counsel could be removed. The second proposal would have created a three-member independent commission with rulemaking authority over compliance with the RFA and mandated a majority vote for all official commission actions (including comments submitted for the public record). Advocacy supported the first proposal, but had major concerns with the second. This is primarily because the second proposal would 1) take away Advocacy's ability to react quickly to fast-moving issues or emergencies; and 2) convert its work into litigious activities and thereby eliminate Advocacy's early access to policymakers in the executive branch.[25] No final action has been taken on either proposal.

25. See Chief Counsel's testimony of June 21, 2000, at www.sba.gov/advo.

Conclusion

"The Office of Advocacy's intervention in this matter is a valuable case study in the need for small businesses to have a federally established oversight organization to whom they can appeal in cases where agency impact analyses are seriously flawed." —— Stephen F. Sims, Pharmaceutical Distributors Association, regarding Advocacy's comments on a rule issued by the Food & Drug Administration (FDA).

The future is a difficult thing to predict. Should we believe Patrick Henry who once said, "I know no way of judging the future but by the past?" Or should we believe Edmund Burke who said, "You can never plan the future by the past?" Burke's theory seems more likely in light of these questions: Could anyone have predicted that after nearly 20 years of poor and/or spotty agency compliance with the RFA, some agencies would now be active partners with Advocacy in making better regulations that pose less of a burden on small entities? Could anyone have predicted that Advocacy, together with industry representatives, could save small entities billions of dollars annually by eliminating unnecessary and costly regulatory burdens?

One thing is certain: hindsight has proven the RFA critics wrong. The RFA has been and will continue to be a valuable tool in the important work of fashioning fairer and better regulations. Moreover, agencies that have worked closely with Advocacy in recent years have found that RFA compliance does not necessarily impose increased cost or burden on the agency—particularly when the cost of litigation for noncompliance with the RFA is taken into consideration.

Although it is impossible to know what the future holds, it can at least be said that the future looks promising. Each year since the passage of SBREFA, more and more agencies have made a good-faith effort to comply with the RFA—seeking RFA training, consulting with Advocacy early in a rule's development, etc. There is no reason for that trend to falter in the near future. Clearly, many agencies still need to do a better job and other agencies lack understanding of even basic RFA concepts. It is Advocacy's hope that all federal agencies will grow to appreciate the value and importance of the RFA.

"FDA withdrew the most controversial portions of the proposed regulation . . . This is an astounding and unprecedented turnaround that would not have occurred without the SBA's help . . . As a result of the support the Office of Advocacy has provided, I am now convinced the SBA is an essential watchdog to prevent ill-conceived FDA regulations."– A. Wes Siegner, Jr., Hyman, Phelps & McNamara, P.C.

In order for the regulatory environment to continue improving, the Office of Advocacy must be allowed to pursue its unique mission of representing small businesses within the federal government zealously and independently. Advocacy's ability to pursue its mission will hinge largely on two factors. The first is adequate funding from Congress. This will ensure proper staffing of the office and continued availability of vital economic research for policymakers. The best way to ensure proper funding may be to make Advocacy's budget a separate line item in the budget. Whatever the formula for Advocacy's funding in the future, the office will continue to utilize its resources to

serve as the nation's watchdog against excessive government regulation. The other factor is the skill of the Chief Counsel to forge consensus between the executive and legislative branches of government and to open up policy councils to meaningful participation by small businesses. Credibility and nonpartisan relations with Congress, executive branch agencies and the small business community, as well as rapid responses to regulatory and policy initiatives, are key to effective representation of small business issues by a Chief Counsel. This is perhaps the single most important aspect in motivating the entire office, and it ensures the commitment of a team of professionals to small business.

Appendix A: The Regulatory Flexibility Act, as Amended

The following text of the Regulatory Flexibility Act of 1980, as amended, 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). The Act was amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (P.L. 104-121).

Congressional Findings and Declaration of Purpose

(a) The Congress finds and declares that—

(1) when adopting regulations to protect the health, safety and economic welfare of the Nation, Federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public;

(2) laws and regulations designed for application to large scale entities have been applied uniformly to small businesses, small organizations, and small governmental jurisdictions even though the problems that gave rise to government action may not have been caused by those smaller entities;

(3) uniform Federal regulatory and reporting requirements have in numerous instances imposed unnecessary and disproportionately burdensome demands including legal, accounting and consulting costs upon small businesses, small organizations, and small governmental jurisdictions with limited resources;

(4) the failure to recognize differences in the scale and resources of regulated entities has in numerous instances adversely affected competition in the marketplace, discouraged innovation and restricted improvements in productivity;

(5) unnecessary regulations create entry barriers in many industries and discourage potential entrepreneurs from introducing beneficial products and processes;

(6) the practice of treating all regulated businesses, organizations, and governmental jurisdictions as equivalent may lead to inefficient use of regulatory agency resources, enforcement problems and, in some cases, to actions inconsistent with the legislative intent of health, safety, environmental and economic welfare legislation;

(7) alternative regulatory approaches which do not conflict with the stated objectives of applicable statutes may be available which minimize the significant economic impact of rules on small businesses, small organizations, and small governmental jurisdictions;

(8) the process by which Federal regulations are developed and adopted should be reformed to require agencies to solicit the ideas and comments of small businesses, small organizations, and small governmental jurisdictions to examine the impact of proposed and existing rules on such entities, and to review the continued need for existing rules.

(b) It is the purpose of this Act [enacting this chapter and provisions set out as notes under this section] to establish as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.

Regulatory Flexibility Act

§ 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 rule-making 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).

Appendix B: Fiscal Year 2000 Report on Agencies' Compliance with the Regulatory Flexibility Act

Table of Contents

Department of Agriculture

The U.S. Department of Agriculture (USDA) was established in 1862 by President Lincoln. Since then, USDA has been charged with a very wide and diverse set of responsibilities such as farm support programs, soil conservation measures, feeding programs, inspection of meat and poultry, raising rural homeownership, research on pest management, biotechnology, nutrition and food safety, and management of 192 million acres of national forest and grasslands.

Historically, USDA has demonstrated a spotty history of compliance with the Regulatory Flexibility Act (RFA). As described below, throughout fiscal year 2000, the Office of Advocacy continued to work with various agencies within USDA to improve their RFA compliance activities.

In addition to the specific issues listed in this section, Advocacy has also commented on a number of other major USDA-proposed regulations. Since most of the work on these draft regulations contains confidential interagency work product, they cannot be discussed in detail herein. These proposed regulations included many important regulations, such as USDA's rule creating national standards for organic farming and processing.

Agricultural Marketing Service

In the early 1990s, Advocacy finally convinced the Agricultural Marketing Service (AMS) that its programs were subject to the RFA. Since the passage of the Small Business Regulatory Enforcement Fairness Act (SBREFA) in 1996, AMS has included more analysis in its regulations, frequently opting to prepare an initial regulatory flexibility analysis (IRFA) rather than certify their regulations. However, many of the analyses generally seem to miss a fundamental element: an explanation of why marketing orders and promotion programs are necessary and promote better economic results than a free-market scheme. This is an arcane area of law complicated by the fact that the regulated businesses frequently decide how they are to be regulated—that is, packing requirements, fruit size requirements, whether to adopt a promotion program, etc.

The exception to the rule regarding AMS' track record of RFA compliance is the Organic Program Office. This unit within AMS has worked diligently with Advocacy and the Office of Management and Budget (OMB) for over two years to develop regulations for a national organic program. The Organic Program staff met with Advocacy

very early in the rule's development in an attempt to make small business concerns an integral part of the rule. In terms of process and outcome, this approach is generally better than writing a rule and then figuring out how to fit small businesses into the equation.

Food and Nutrition Service

Issue: Food Stamp Retailer Eligibility. In June 1999, the Food and Nutrition Service (FNS) proposed a rule to revise the criteria for retail stores that wish to continue participating in the food stamp program. The primary purpose of the rule is to ensure that food stamp recipients continue to have adequate access to stores where they can purchase a wide variety of nutritious food items. FNS determined that a qualifying business must maintain no fewer than three different varieties of staple food items out of four statutorily defined categories, including perishable foods in at least two of those categories. For example, a retailer selling whole, skim, and chocolate milk can only claim one variety of dairy product. In order to ensure the sufficiency of stock on a continuing basis, FNS determined that a qualifying business must be able to verify at least $30,000 in wholesale purchases annually. These were deemed "Criterion A" requirements by the agency. If a business cannot meet "Criterion A" requirements, it can qualify for "Criterion B," which requires a business to have more than 50 percent of its total sales in staple foods.

Although the agency certified under the RFA that the regulation would not have a significant economic impact on a substantial number of small entities, there was no factual basis for its certification. There was no mention of the number of small entities affected by the rule, which is the basic requirement for determining whether a substantial number of small entities were affected. There was no explanation for the seemingly arbitrary requirements in the rule, such as the $30,000 minimum in wholesale purchases, and why such a requirement would have no significant economic impact on small businesses.

The intent of Congress when it mandated changes in the retailer eligibility requirements was to eliminate marginal stores that do not provide enough nutritious foods. Thus, Advocacy questioned whether there is any beneficial effect if stores covered by the rule are eliminated, even if they carry substantial amounts of staple foods. By not doing an economic analysis, the agency may also be harming the food stamp beneficiary if he or she has to travel further distances to find a store that does meet the criteria.

Advocacy filed comments with FNS on August 27, 1999, urging the agency to re-propose the regulation with either a factual basis for its certification or an IRFA. Advocacy awaits further action from the agency on the rule.

Issue: Vendor Participation Requirements for the Women, Infants, and Children Program. In June 1999, FNS published a rule that would strengthen requirements for operation of vendor management systems by limiting the number of vendors and imposing training requirements. As with the food stamp retailer rule above, the agency certified the regulation as having no significant impact on small businesses.

Advocacy again asserted that there was no factual basis or data to support the certification. There was no discussion of the costs associated with limiting the number and distribution of authorized vendors that have never defrauded the government; or a description or estimate of the number of small entities that will be affected by the rule. Therefore, the rule has the potential of affecting not only abusive vendors, but legitimate vendors as well, based on whether participants have adequate access to the program. For example, if a large chain store is serving the area adequately, a smaller store might be eliminated from the program. Controversy swirled around a similar rule that was proposed by the FNS about eight years prior to the instant rule, so the agency needs to be particularly mindful of the rule's impact.

Advocacy filed comments with FNS on August 27, 1999, voiced these concerns, and requested that the agency re-propose the regulation with a certification and adequate factual basis for the rule, or prepare an IRFA. To date there has been no response by FNS to Advocacy's request.

Food Safety and Inspection Service

The Food Safety and Inspection Service (FSIS) is another office within USDA that Advocacy believes still needs more work to improve RFA compliance. For example, FSIS issued "policy changes" at least twice in 1999 affecting thousands of small entities. One policy change eliminated face-to-face label reviews, and the other dealt with adding beef trimmings to the range of products that would be considered adulterated when contaminated with a particular food pathogen.

The first of these two policy changes threatened to put many courier/expediter services out of business by not allowing meat processors to use couriers to meet in person with USDA label reviewers for instant label reviews. It also threatened to do great damage

to the small processors who relied on courier services to obtain rapid approval on label changes. Ironically, elimination of the face-to-face process contravened USDA's own internal reports that hailed the process as successful and efficient. The second policy change was a sweeping expansion of FSIS policy interpretation of adulterated meat.

Despite the impact of both "policy changes," the agency failed to do any economic analyses. In Advocacy's opinion, this violated the Administrative Procedure Act (APA) as FSIS failed to publish the changes as proposed rules. Moreover, when rules are not published for public notice and comment, they are not subject to the requirements of the RFA. Although the agency seems to have survived a court challenge in the case of the label reviews,[1] the agency's resources probably would have been better utilized by issuing a proposed rule and preparing a proper analysis.

In September 2000, FSIS contacted Advocacy requesting a tailored briefing on how to comply with the RFA. Advocacy conducted this briefing for about 25 FSIS and USDA staff, with great emphasis on the definition of a small entity for purposes of the RFA. Advocacy hopes the briefing will serve to make FSIS more sensitive to small business issues in the future.

Forest Service

The USDA's Forest Service is responsible for providing a continuing flow of natural resource goods and services to help meet the needs of the nation and to contribute to the needs of the international community. It is responsible for providing a sustained flow of renewable resources (outdoor recreation, forage, wood, water, wildlife, and fish) in a manner that best meets the needs of society now and in the future. FS is also responsible for assuring that nonrenewable resources are administered in a manner to help meet the country's needs for energy and minerals.

With the exception of timber-related issues such as the spotted owl, Advocacy's interaction with FS was limited in the past. However, in fiscal year 2000, Advocacy became more active in FS' regulatory process.

Issue: Limitation on Road Construction in National Forests. In October 1999, the administration directed FS to draft a rule to prohibit road construction and reconstruction in approximately 54 million acres of inventoried roadless areas. There was an exception in the rule for valid existing rights, public health and safety requirements, and conservation protection for threatened and endangered species. To meet the admin-

1. *James V. Hurson Associates, Inc. v. Glickman,* 229 F.3d. 277 (D.C. Cir. 2000).

istration's directive, FS assembled an interagency team to assure compliance with various requirements of laws such as the National Environmental Policy Act (NEPA) and RFA. FS asked Advocacy to be a part of that interagency team, and Advocacy's primary role in the interagency effort was to advise the agency on RFA compliance.

Initially it was FS' position that an RFA analysis was not necessary because the initiative would not have a significant impact on a substantial number of small entities. Advocacy believed that the proposal could have a foreseeable adverse impact on several small entities, including members of the timber industry, small natural-resource-dependent communities, members of the mining industry, recreation providers such as companies that rent snowmobiles and outfitters, and construction companies. Advocacy raised its concerns to FS verbally and in writing prior to the publication of the proposed rule in the *Federal Register*. Advocacy was concerned about the lack of information on the impact that the initiative would have on small businesses and communities, such as reduced revenues, increased costs, and dissolution of businesses due to the lack of access to natural resources found on federal lands.

Although FS continued to contend that there was no direct significant economic impact, in the end, the agency heeded Advocacy's advice and prepared an economic analysis. Since FS did not have sufficient information to prepare a meaningful economic analysis, Advocacy asserted that FS had a duty to make a good-faith effort to obtain the data it needed to determine the economic impact of the proposed rule on a diverse group of small entities. Advocacy suggested that FS publish a list of questions along with the proposed rule in order to solicit the necessary information from the public. FS prepared such a list and published the proposed rule in May 2000. When the public comment period closed on July 17, 2000, FS had received thousands of comments on the proposal. Advocacy also filed comments, and acknowledged FS' cooperation in preparing a regulatory flexibility analysis. Advocacy also stressed the importance of FS giving full consideration to the information and the alternatives provided by the public in response to the IRFA. Currently, Advocacy is working with FS as it reviews the public comments and prepares the final rule, which is expected to be published in late December 2000.

Department of Commerce

The U.S. Department of Commerce (DOC) is responsible for encouraging the nation's

economic growth, international trade, and technological advancements. A number of agencies within DOC are responsible for achieving this mandate. The agencies manage programs affecting diverse areas of commerce, such as fisheries, telecommunications, economic development, electronic commerce, and patents.

National Marine Fisheries Service

The fishing industry is dominated by small entities, and the economies of many small communities across the country are highly dependent on the fishing industry. Regulations that adversely affect the fishing industry also affect the fishing communities. The National Marine Fisheries Service (NMFS), a division of DOC's National Oceanic and Atmospheric Administration (NOAA), promulgates the majority of the regulations affecting small entities in the fishing industry. NMFS regulates the activities of small businesses under several natural resource protection statutes such as the Marine Mammal Protection Act and the Magnuson-Stevens Fishery Conservation and Management Act.

NMFS promulgates rules through fishery councils located in different geographical parts of the country. Some councils have better information collection systems than do others. This affects the quality and consistency of the economic analyses performed by NMFS. The lack of consistent economic information has hindered NMFS' ability to perform thorough and credible economic analyses in compliance with the RFA. As an agency, NMFS has demonstrated a significant amount of improvement in its RFA compliance over the last few years. Advocacy believes that NFMS has made an institutional decision to comply with the RFA rather than circumvent its provisions. Historically, NFMS would certify that there was no significant impact on a substantial number of small businesses even if the certification was not supported by the data. Subsequent to the passage of SBREFA, NMFS' RFA compliance came under judicial and legislative attack. In response to pressure from the courts and Congress, NMFS hired an economist and an attorney specifically to address RFA compliance. NMFS also hired an ombudsman for small entity issues.

In fiscal year 2000, the agency continued to make changes to its institutional framework in an attempt to advance its compliance with the RFA. A major change included new guidelines for review of impacts. NMFS completed its new agency guidelines to assist its regulators in performing economic analyses that comply with the RFA. The guidelines stress that a certification is the exception and should only be used in instances where the lack of an economic impact is clear. In all other instances, the regulators are

directed to perform the necessary IRFA or final regulatory flexibility analysis (FRFA). NMFS is also working with its analysts to develop better alternatives to proposed rules and to gather the financial information that it needs to perform thorough economic analyses.

Advocacy also holds regular issues "roundtables" attended by members of the fishing industry trade associations and officials from NMFS, NOAA, and DOC's Office of the General Counsel. At these meetings, fishing industry representatives have questioned whether NMFS is using the best available science in determining the appropriate manner to address fishery management. The best available science provides data on the status of the stock, which, in turn, determines which alternative(s) should be selected to address the particular management issue. Likewise, there are concerns about NMFS' failure to develop meaningful alternatives that allow for the survival of the fishery during the rebuilding period. Advocacy has raised these industry concerns with NMFS.[2]

Issue: Reduced Shark Quotas. On December 20, 1996, NMFS published a proposal to reduce the existing shark fishing quota by 50 percent and certified that the reduction would not have a significant impact on a substantial number of small entities. Thus began a lengthy saga of communications between Advocacy and NMFS, in which Advocacy maintained that NMFS had not complied with the RFA and that its economic analyses were significantly flawed.[3] The industry sued NMFS on this issue. The case, *Southern Offshore Fishing v. Daley*,[4] was eventually referred to a special master by the U.S. District Court for the Middle District of Florida after an unsatisfactory remand to the agency.

On October 1, 1999, the special master submitted his findings and recommendations to the court. The special master held that:

- NMFS failed to collect meaningful economic data and this failure was arbitrary and capricious. Further, NMFS did not have all the necessary information to evaluate and implement alternatives to the quota.

- NMFS' failure to give any consideration to alternatives to the quota was a wanton repudiation of the court's instruction on remand.

2. Over the last few years, the number of comment letters that Advocacy has written to NMFS has declined significantly. This decline is attributable in part to improvement in NMFS' RFA compliance efforts and partly to Advocacy's decision to try to resolve disputes through negotiation.
3. See *Annual Report of the Chief Counsel for Advocacy, 1998*, p.19.
4. 995 F. Supp. 1411 (M.D. Fla. 1998).

- NMFS acted with a lack of good faith and contrary to the court's express instructions in the preparation of the remand submission.

The special master concluded that NMFS' conduct constituted bad faith and a lack of candor to the court. The DOC filed objections to the special master's findings.

In November 2000, federal regulators agreed to delay a decision on new shark fishing quotas until after a review of current and future shark stocks by a group of independent scientists. The decision for an independent review is part of a court settlement reached between the National Marine Fisheries Service and the Southern Offshore Fishing Association. The court still must approve the settlement agreement.

Issue: Spiny Dogfish. On August 3, 1999, NMFS published a proposed Spiny Dogfish Fishery Management Plan. The intent of the plan was to rebuild the spawning fishing stock and eliminate overfishing while allowing for a one-year exit fishery. The average annual landings for the 10 years prior to the rule were 40 million pounds. The proposed plan implemented a commercial quota that allowed for 22 million pounds in year one and 2.9 to 3.2 million pounds for years two through five.

NMFS prepared an IRFA for the proposal. In the proposal, NMFS acknowledged that: (1) in year one of the rebuilding schedule, there will be a 30 percent reduction in landings; (2) in the second year, there will be an 89 percent reduction in landings; and (3) the reduction in landings could result in the elimination of the remaining three dogfish processing plants and the total collapse of the U.S.-based markets for spiny dogfish harvesting and processing.

Advocacy filed its comments on September 17, 1999, arguing that it was counterintuitive to implement a plan to rebuild a stock for a fishery that was being forced out of business by the implementation of the plan. Advocacy also criticized NMFS' failure to consider less restrictive alternatives, such as landing limits, size limits, seasonal closings, gear alternatives, and a fishery directed towards male dogfish. Advocacy argued that although NMFS stated that it considered 12 alternatives to the quota, they were actually variations of two themes: quotas and size limits. Advocacy compared the alternatives cited to the ones used by NMFS in the Southern Offshore Fishing case where the court characterized NMFS' treatment of alternatives as superficial.

Advocacy also questioned whether NMFS met its obligations under National Standard 8 of the Magnuson Act, which requires NMFS to consider the importance of fishing resources to the fishing community and select the alternative that minimizes the

impact. The New England Council and the Mid-Atlantic Council disagreed on the amount of the quota, and the issue was referred to the Secretary of Commerce. In April 2000, the rule became effective when the Secretary of Commerce issued an opinion that reduced the quota to 4.5 million pounds.

The industry (fishers, processors, and dealers) filed suit in Massachusetts against DOC on February 8, 2000, and sought injunctive relief in May 2000, on the basis that the industry would cease operations under the allowable quota.[5] In July 2000, the U.S. District Court upheld the Secretary of Commerce's decision on the basis that the action was necessary to sustain the fishery and for DOC to meet its obligations under the Magnuson Act.

Department of Health and Human Services

The U.S. Department of Health and Human Services (HHS) is the principal federal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. HHS includes more than 300 programs that cover a wide spectrum of activities, such as medical and social science research, prevention of outbreak of infectious disease, food and drug safety, Medicare (health insurance for elderly and disabled Americans), Medicaid (health insurance for low-income people), and financial assistance for low-income families.

In recent years, Advocacy has actively partnered with several branches of HHS to create a better regulatory environment for small entities. For instance, in March 1999, Advocacy held two in-depth training sessions for staff of its Health Care Financing Administration (HCFA) at the agency's headquarters in Baltimore. Those training sessions and several meetings with HCFA officials have led to a less contentious relationship between HCFA and Advocacy. This has in turn allowed Advocacy to have early input on several key regulations.

Despite HCFA's challenging congressional mandate, Advocacy believes that the agency could do a better job of considering less burdensome regulatory alternatives that still meet statutory requirements. Many health care providers have expressed great frustration with HCFA and its regional carriers in particular. It is hoped that HCFA will rid itself of this negative public perception by looking more closely at regulatory alternatives and by forcing its regional carriers to apply HCFA's guidelines with significantly greater consistency.

5. See *A.M.L. International, Inc. v. Daley*, 107 F. Supp. 2d 90 (D. Mass. 2000).

On the other hand, the Center for Food Safety and Applied Nutrition (CFSAN), within HHS' Food and Drug Administration (FDA), should be lauded for its efforts to help small entities. CFSAN has worked with Advocacy by offering briefings on upcoming regulations that will affect small entities before the regulations are even proposed. CFSAN seems to have made an institutional adjustment and a conscious decision to analyze the impact of their regulations on small entities thoroughly, thereby mitigating adverse impacts where possible.

This institutional change at CFSAN came after several harsh comments from Advocacy that criticized the agency's analyses and its failure to comply with the RFA. Officials from CFSAN have stated that it is more productive to work with Advocacy in the earliest stages of rule promulgation than against Advocacy after a negative comment has been received. Certainly, more agencies should adopt this philosophy, including CFSAN's parent agency, HHS. CFSAN has also published a small business guide on writing effective comments to agency proposals. By following this basic guide, small businesses are able to write effective comments that explain the rule's impact on their business and provide invaluable data to the agency.

Advocacy's relationship with other agencies within HHS is described below. In addition to the regulatory issues listed in this section, Advocacy has also commented on a number of other major HHS-proposed regulations. However, since most of the work on these regulations contains confidential interagency work product, they cannot be discussed in detail herein. Some of these regulations include a health information privacy rule that seeks to impose strict requirements on health care providers and their business partners regarding the handling of confidential information; HHS' rule on standards for electronic transactions in health care that governs confidentiality of electronic patient health records; and FDA's egg labeling and refrigeration rule to promote egg safety.

Food and Drug Administration

Issue: Disease Claims on Dietary Supplement Labels. This rule was highlighted in Advocacy's 1998 annual report, but it has since become final. In 1998, FDA published a proposed rule outlining, and defining, 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 rule also established criteria for determining when a statement about a dietary supplement is a prohibited disease claim. On October 14, 1998, Advocacy submitted comments regarding the proposed definition of "disease" and the negative impact such a definition would have on small businesses. Among other things,

Advocacy proposed that FDA not expand the definition to include otherwise legal, truthful, and nonmisleading statements about the effects of a product on the normal structure or function of the body. In December 1999, both the OMB and FDA contacted Advocacy to review and comment on the draft final rule.

When the final rule was published on January 6, 2000, the provisions that were most harmful to small businesses had been modified. FDA redefined "disease" to comport with the previous statutory definition. References to journal articles/titles will be permitted on product labeling. In addition, statements that apply to conditions associated with natural states or processes like pregnancy or aging will also be allowed. Finally, more acceptable data on the number of affected small entities was utilized, which resulted in a more accurate impact analysis of the rule.

Issue: Drug Pedigree Requirements. The Prescription Drug Marketing Act (PDMA) was created to combat abuses involved in the distribution of prescription drugs. It contains drug pedigree requirements that impose prior sale documentation obligations on nonauthorized distributors. Central to whether a business would have to comply with the documentation requirements is whether a business is "an authorized distributor of record" that maintained an "ongoing relationship" to distribute a manufacturer's products. Guidance issued by FDA in 1988 stated that "ongoing relationship" was to be interpreted broadly, and that the existence of two transactions in a two-year period would be presumptive evidence of a continuing relationship. The 1992 PDMA amendments altered the information requirements that had to be provided prior to each wholesale distribution of a drug.

When FDA proposed its regulations to implement the PDMA amendments on March 14, 1994, it instituted a sudden reversal of policy. The regulations changed the definition of "ongoing relationship" to make it harder to become an authorized distributor. It gave manufacturers the sole discretion to determine who should be designated as an "authorized distributor." The proposal required a written statement between a manufacturer and each authorized distributor, and each distributor must appear on the manufacturer's list of authorized distributors. The industry requested that FDA revise the rule to require that the pedigree go back only as far as the last authorized distributor of record, and not for each one in the chain.

When the final rule was published on December 3, 1999, it was obvious that FDA

rejected the industry's request. Advocacy submitted comments to FDA on February 29, 2000, petitioning the agency (pursuant to section 553 of the APA) to reconsider the final rule, suspend the effective date, and reissue regulations that will carry out the intent of Congress with respect to the PDMA. Advocacy argued that FDA's regulatory scheme ignored the reality of the relationship between secondary drug wholesalers and manufacturers. Manufacturers can choose to limit those businesses that they consider authorized distributors. Also, drug products currently in the inventory of wholesalers would have to be cleared out and new orders would have to cease, or be severely limited, within one year to accommodate the actual effective date of the rule. Moreover, secondary wholesalers (who buy from full-line wholesalers that do not provide a pedigree) would not be able to provide a pedigree to their customers describing transactional information back to the manufacturers. On May 3, 2000, a delay of the effective date of the proposed rule was announced in the *Federal Register*. Affected entities will not have to comply until October 2001, pending further study and analysis of the rule.

Issue: Pre-Market Approval for Silicone Breast Implants. Advocacy began working on this issue in 1999 when FDA published a final rule designating the effective date for requiring the filing of a pre-market approval application (PMA) or a notice of completion of product development protocol (PDP) for silicone inflatable breast prostheses. The regulation would require commercial distribution of the device to cease unless a manufacturer, or importer, filed a PMA or PDP within 90 days of the effective date. FDA estimated that the cost of compliance with the rule would be $1 million per PMA, and certified that there would not be a significant impact on small businesses because the industry was aware that PMAs were inevitable.

Advocacy filed comments on September 9, 1999, saying that FDA failed to provide a factual basis for their certification. There were no estimates of the number of small entities affected and no information on why the $1 million estimate per PMA was not a significant cost for businesses to bear. Advocacy requested that FDA republish the rule with a proper certification.

In a November 16, 1999, letter to Advocacy, FDA claimed that only seven entities would be affected. According to the FDA, five of the entities were large and/or foreign businesses, and they were already legally marketing the products. FDA claimed that the two remaining companies did not constitute a "substantial number of small entities" per the RFA. In short, the agency declined to republish the rule.

Advocacy submitted additional comments to the FDA on February 9, 2000, stating that the two businesses do in fact constitute a substantial number for the purposes of the RFA because those two businesses constituted 100 percent of regulated small entities. The letter also alluded to a disturbing pattern whereby FDA assumed a similar position regarding the interpretation of "substantial number" in another rule concerning ophthalmic eye shields. No further comment has been received from the FDA to date.

Issue: Sterility Requirements for Aqueous-Based Drug Inhalation Products. FDA proposed a regulation that would raise the number of inhalation solution products manufactured with a sterile process from 50 percent to 100 percent in order to reduce the incidence of adverse drug reactions from contaminated nonsterile solutions. FDA identified five firms (representing 18 percent of the regulated industry and 100 percent of small businesses) that did not use a sterile process or that contract out the process. FDA stated that the five firms could expect to incur costs from $270,000 to $1.7 million each.

Advocacy filed comments on December 18, 1997, that criticized the lack of estimates for training and paperwork, the lack of data on illnesses caused by nonsterile products and the lack of less burdensome alternatives. Advocacy requested lengthening the compliance date from one year to two and end testing products for signs of contamination rather than requiring a sterile process.

On February 7, 2000, FDA sent Advocacy a copy of the draft final rule for review. The rule reflected a sizeable reduction in the small business burden. The scope of the regulation was clarified to limit the rule's applicability, and the time for compliance was increased to two years. For the first time, the regulation contained data on actual adverse event reports associated with nonsterile products that had occurred in the past. The one-year delay resulted in a one-time saving to small businesses of $10.1 million.

Health Care Financing Administration

Issue: Medicare Ambulance Fee Schedule. This rule was highlighted in Advocacy's 1998 annual report, but it has since become final. In 1997, HCFA proposed a regulation to reduce Medicare costs resulting from the use of ambulances where no medical necessity existed, or where reduced services may suffice. 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 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 and certain minimum supply and equipment levels.

Based on Advocacy's November 4, 1997, comments, as well as other comments filed by industry, HCFA published a final rule in 1999 that modified certain portions of the proposal. More important, HCFA called for a negotiated rulemaking to decide the proper definition of the various classes of ambulances. The 1999 rule reduced the equipment requirements, modified staff requirements to comport with state laws, and removed physician certification requirements in certain circumstances.

On September 12, 2000, the agency published its proposed Medicare ambulance fee schedule, which drew heavily from a fee schedule negotiated with industry groups. For example, most of the cost shifting will come from urban areas and go to rural areas (which incur higher costs per trip). There will be seven categories of ground ambulance services rather than two. There will be a set reimbursement rate for each category, based on the relative cost of the service, adjusted for wage differences. As a result of these provisions rural areas will receive higher reimbursements for the service. HCFA proposes to phase in the revised schedule over four years. As a result of the negotiated rulemaking, the fairness of the rule has been enhanced.

Issue: Competitive Bidding Demonstration Projects for Durable Medical Equipment. As described in Advocacy's 1998 and 1999 annual reports, this program seeks to limit the number of providers in a designated region for selected types of durable medical equipment and home medical equipment supplies. Under the demonstration, only successful bidders will be able to participate in the Medicare reimbursement program.

Advocacy commented about the program twice, once to HCFA on November 11, 1998, and once to OMB on December 18, 1998. Meetings were held at OMB to negotiate the details of the regulation. Aside from the burden imposed by the bidding requirements, the biggest problem was that HCFA saw no need to publish a proposed rule. It chose instead to publish a direct final rule. Additional issues were raised during the OMB meetings, such as the program's compatibility with the agency's proposal on consolidated billing for skilled nursing facilities, and whether sensitive financial data should be collected from prospective bidders that were not finalists. HCFA redesigned

some portions of the bid packages based on concerns voiced by Advocacy and industry. Even after the changes, the agency acknowledged that reimbursement to winning suppliers would be reduced by 13 to 31 percent. During August and September of 1999, HCFA apprised Advocacy of the preliminary results of the demonstration. It showed that 14 of the 16 winning suppliers were small entities.

In October 1999, HCFA held a public meeting on a second demonstration project to be implemented in a different region of the country. The meeting allowed interested parties to furnish information and raise issues about the items selected for the demonstration, including the proposed site and quality standards for bidders. This marked a significant improvement over the manner in which the first demonstration was conducted because public input occurred before the rule reached the OMB review stage.

In January 2000, HCFA officially proposed its second demonstration project, but again, the agency requested emergency OMB clearance for the bidding forms. Advocacy submitted comments to HCFA on February 14, 2000, criticizing the agency for seeking emergency clearance. The agency responded by indicating that it had to fit in all five demonstrations before its authorization expired in 2002. Advocacy argued in the alternative that the agency was permitted, but not required, to establish five demonstrations; therefore, emergency clearance should not have been sought. Advocacy also opined that some of the selected items (e.g., oxygen and wheelchairs) were not properly included in the items subject to bidding because of the heavy service component required for those items. Some small businesses have built a niche market for durable medical equipment that requires special orders or a heavy service component. No significant changes were made to the proposal by HCFA. Advocacy will actively continue to monitor future demonstrations.

Issue: Prospective Payment System for Home Health Agencies. Advocacy was very involved in the predecessor to this rule, the interim payment system (IPS) for home health agencies (HHAs). That rule attempted to curb Medicare spending, fraud, and abuse by changing its reimbursement policy from one based on reasonable or actual costs to one based on caps. The caps were determined by analyzing historical costs for some agencies, and national average costs for other agencies. The regulation unfairly penalized historically low-cost HHAs, by giving high-cost agencies higher payments in most cases.

Several unsuccessful lawsuits were filed by industry across the country. Industry relied on Advocacy's initial IPS comments to support their respective cases to argue that the IPS regulation violated the RFA. However, the court in *Greater Dallas Health Care Alliance v. Shalala,*[6] concluded that HCFA did not violate the RFA and was simply doing what Congress mandated. Further history of Advocacy's involvement in IPS can be found in Advocacy's 1998 annual report.

The prospective payment system (PPS) was required by the Balanced Budget Act of 1997, and was later refined by the Balanced Budget Refinement Act of 1999, and other laws. PPS was intended to replace the IPS with a more fair-minded approach to reimbursement.

In the summer of 1999, HCFA requested Advocacy's comments on the draft proposed rule for PPS. Advocacy submitted its comments on August 26, 1999. On October 21, 1999, Advocacy was briefed by HCFA officials on the content of the PPS draft proposed rule and later briefed on the draft final rule on June 23, 2000. In reviewing the rules, Advocacy found that PPS was preferable to IPS because, among other changes, PPS will take into account the patient mix of an agency and allow for a change-in-condition adjustment if a patient's condition worsens. PPS will also allow for a restart of the 60-day episode if a patient is transferred to a different agency, and will delay for one year the 15 percent across-the-board reduction in payments (pursuant to the Balanced Budget Refinement Act). A town hall meeting was held by HCFA to explain the requirements of the rule shortly after publication of the final rule. The overall effect of the PPS rule will be to reduce some of the burden associated with IPS.

Issue: Hospital Outpatient Prospective Payment System. This rule was highlighted in Advocacy's 1999 annual report. Like the home health care PPS, the hospital outpatient rule sought to change the system of Medicare reimbursement from one that was cost-based to one that is based on predetermined rates for individual services.

Advocacy submitted comments to HCFA on July 29, 1999, suggesting that the agency should exclude cancer, rehabilitation, and rural or low-volume hospitals from the rule because they are highly specialized facilities and use advanced treatment modalities. For instance, the national median hospital costs proposed by HCFA did not support the sophisticated and evolving types of treatment in cancer hospitals. The proposal would have reduced payments to low-volume, cancer, and rehabilitation hospitals by 17.0, 29.2, and 24.1 percent, respectively.

6. 36 F. Supp. 2d 765 (N.D. Tex. 1999).

On November 29, 1999, the Administration signed the Balanced Budget Refinement Act of 1999, resulting in a 10 percent increase in payments to hospitals, and other additional payments to help hospitals make the transition from the cost-based system. Several specialty hospitals were excluded from the requirements of the outpatient rule. These changes were part of the $7.2 billion in payments given back to hospitals after the industry charged that reductions in the Balanced Budget Act of 1997 went deeper than Congress intended. The final rule reflecting these changes was published on April 7, 2000. Further "give-back" legislation is pending in Congress at this time.

Issue: Inherent Reasonableness of Medicare Services. This proposed rule from 1998 required a revision of the process for establishing a realistic and equitable payment amount for Medicare Part B services when existing payment amounts are deemed inherently unreasonable (because they are grossly excessive or deficient). The rule described the factors HCFA would consider and the procedures it would follow to establish appropriate payment amounts. Congress gave HCFA the authority to bypass notice and comment rulemaking on inherent reasonableness determinations if the amount of the reduction does not exceed 15 percent in one year.

On November 2, 1998, Advocacy submitted comments to HCFA on this issue. Advocacy argued that HCFA made a habit of publishing direct and interim final rules to bypass notice and comment procedures required by the APA. In a ten-month period studied by Advocacy, HCFA published direct and interim final rules 58 percent of the time (excluding nonsubstantive notices, extensions of time, and technical changes). HCFA claimed it had good cause for bypassing notice and comment because it was not significantly changing the existing methodology for applying inherent reasonableness, and because it would be contrary to the public interest to delay placing limits on grossly excessive charges.

Advocacy's letter also criticized HCFA for using the regulation to reduce payments by more than 15 percent by simply splitting the reduction over two years. Under HCFA's interpretation of the legislation, a provider's payment could be reduced by 30 percent in a two-year period, or even 45 percent in a three-year period without notice and comment.

On April 9, 1999, the Administrator of HCFA responded to Advocacy's concerns. The administrator defended the agency's lack of notice and comment because she felt that

HCFA was merely announcing a procedural change authorized by statute. In addition, the administrator claimed that: (1) the regulation only described a process and the agency does not have the data to predict the rule's impact; (2) the regulation does not result in any inherent reasonableness adjustments, and; (3) only inefficient businesses that overcharge Medicare would be affected.

In July 2000, the General Accounting Office (GAO) released a report on the inherent reasonableness process. GAO interviewed Advocacy regarding its earlier comments. GAO found HCFA's process to be generally appropriate. However, GAO criticized the inadequacies of the Durable Medical Equipment Regional Carrier's (DMERCs) survey process on pricing which formed the basis for inherent reasonableness determinations. GAO also said that bypassing notice and comment was appropriate in the rule even though GAO issued a report in 1998 criticizing agencies (especially HHS) for bypassing notice and comment regularly.

Advocacy submitted comments to OMB and the industry regarding GAO's report on July 10, 2000, since an alternative renovated inherent reasonableness regulation is currently pending. The comments criticized GAO on a number of grounds, but focused on GAO's criticism of the DMERC survey process. The pricing data upon which the DMERCs rely is the basis for determining whether a payment is grossly excessive or deficient. This is very significant, and interested parties should have been allowed to comment on the issue.

On September 27, 2000, Advocacy submitted comments to HCFA regarding its continued opposition to the manner in which inherent reasonableness has been handled procedurally. Advocacy further indicated its disappointment with GAO's conclusions that a proposed rule was not necessary and that the changes in the original rule did not represent a significant change in the way things are currently done. A resolution of this matter is still pending.

Issue: Medicare Participation Requirements for Rural Health Clinics. In February 2000, HCFA proposed a rule to revise the certification and payment requirements for rural health clinics (RHCs) pursuant to the Balanced Budget Act of 1997. Among other things, the rule includes a new definition of a qualifying rural shortage area in which an RHC must be located. It also establishes criteria for identifying RHCs essential to the delivery of primary care services, limits waivers of certain nonphysician practitioner

staffing requirements, imposes payment limits on provider-based RHCs, and prohibits commingling office space, equipment, and other resources of an RHC with another entity. HCFA certified that the rule would not have a significant economic impact on a substantial number of small entities, even though the provisions were controversial, the agency could not quantify the future effect of the rule on operation costs, and all affected entities were small.

Advocacy submitted comments on April 28, 2000, arguing that the agency did not provide a factual basis for its certification. If, for instance, an RHC falls outside of the newly designated shortage area, then that RHC can no longer maintain its RHC designation. The agency assumed that RHCs that lose their status could participate on a fee-for-service basis. However, there is no explanation of the costs associated with the transition to a fee-for-service contract, and no mention of whether it would conflict with state regulations. Advocacy also remarked that the prohibition against commingling operations did not take into account legitimate office-sharing relationships. Finally, Advocacy raised several issues addressing patient access to care. Clearly, the agency should have prepared an IRFA rather than simply certifying the rule.

Issue: Medicare Payment for Upgraded Durable Medical Equipment. HCFA proposed a rule that will permit Medicare suppliers to furnish upgraded durable medical equipment (DME) on an assignment basis. Under the rule, Medicare payment would be made to the supplier as if the DME were nonupgraded DME, and the beneficiary purchasing, or renting, the upgraded DME would pay the supplier the difference between the supplier's charge for the DME upgrade and the amount paid by Medicare. The proposal was born out of the Balanced Budget Act of 1997. It allows beneficiaries the opportunity to obtain upgraded equipment (previously disallowed altogether). Medicare has structured the rule so that the benefit covers only durable medical equipment that is adequate and effective to meet the medical needs of the beneficiary. It will not pay extra for convenience or luxury, or more than the applicable fee schedule amount.

The new policy is an excellent one that will give beneficiaries the opportunity to upgrade their equipment and have Medicare pay for a portion. However, Advocacy is concerned about a provision within the rule that requires a 30-day reconsideration period where consumers can return the product to the supplier. The 30-day requirement is problematic because small suppliers may not be able to return used custom products to the manufacturer, or sell the custom item at retail. Ultimately, suppliers

may decide to avoid purchasing such items altogether, thereby limiting consumer access. The requirement is also inconsistent with existing consumer protection laws that may confuse the overall regulatory scheme. Advocacy highlighted these issues in its June 23, 2000, comments to HCFA. Moreover, Advocacy recommended a shorter reconsideration period that is consistent with the Federal Trade Commission's "cooling-off" rule requiring only three business days. Advocacy is awaiting response from HCFA on its comments.

Issue: Outcome and Assessment Information Set (OASIS) Reporting. OASIS is a data collection device to collect information from patients receiving home health care. The information is collected at designated intervals (i.e., the beginning of patient care, 30-day intervals, and at the end of patient care). Advocacy reported briefly on this subject in its 1999 annual report as being part of a group of regulations that stemmed from the Balanced Budget Act of 1997. Advocacy submitted comments to OMB on these regulations and their paperwork impact on December 23, 1998. The final rule was published on January 25, 1999, with a subsequent *Federal Register* notice delaying implementation for non-Medicare patients (because of privacy concerns).

Advocacy was invited to participate in a software demonstration for OASIS in February 2000. The demonstration addressed a number of concerns and questions; however, it was apparent that the agency's information collection estimates were too low. The agency stated that it would take only six minutes to complete an extensive patient assessment. Advocacy determined that it took at least 20 minutes. Advocacy continued to voice concern over the inclusion of non-Medicare patients, since the primary purpose for collecting OASIS data is to aid in establishing case mix information for Medicare reimbursement under the home health prospective payment system. Advocacy will continue to monitor future developments with OASIS.

Issue: HCFA's Patient's Rights Condition of Participation, Patient Restraint (One-Hour) Rule. At the request of Rep. Saxby Chambliss (R-Ga.), Advocacy reviewed HCFA's patients' rights regulation to determine whether HCFA complied with the RFA. Rep. Chambliss received complaints that a particular portion of the interim final rule was a particular burden on small rural entities. More specifically, the rule would require doctors or other licensed independent practitioners to see and evaluate the patient for the continued need for restraint within one hour after the initiation of the restraint.

On September 14, 2000, Advocacy sent Rep. Chambliss a letter agreeing that the one-hour rule would impose a high burden on rural providers since rural physicians might be great distances away from the facility when the restraint is initiated. This one-hour requirement was not present in the proposed rule and therefore the public did not have an opportunity to comment on this aspect of the rule. Moreover, there was no analysis of the impact on rural or small hospitals, and no realistic alternatives were proposed. Advocacy expressed its willingness to draft a petition requesting that the agency reconsider the regulation and its impact pursuant to the APA.

On the same day that Advocacy's letter was sent to Rep. Chambliss, a court decision, *National Association of Psychiatric Health Systems v. Shalala*,[7] was released on the issue, indicating that HCFA failed to comply with the RFA. Although the court refused to disturb the agency's right to promulgate such a rule, the court held that the RFA required HCFA to prepare a final regulatory flexibility analysis to determine the impact of the rule. The judge allowed the rule to remain in effect because it was within the agency's purview to determine that patient safety would be compromised but for the protections provided by the regulation. For the record, Advocacy disagrees with HCFA's patient safety argument. Greater patient injury could occur if the patient cannot reasonably be evaluated after one hour and is released prematurely from restraints. This scenario could result in the patient posing a greater danger to himself/herself or to medical staff. Advocacy will attempt to work with HCFA to resolve this issue.

Department of the Interior

The U.S. Department of the Interior (DOI) is responsible for protecting and providing access to the nation's natural and cultural heritage, and honoring the nation's trust responsibilities to Indian tribes and island communities. Several regulatory agencies within DOI are responsible for managing the country's natural resources. The regulatory issues at DOI affect matters that are extremely important to small entities, such as oil rights, minerals, hardrock mining, reclamation, fish, wildlife, and parks.

Historically, DOI's compliance with the RFA has been problematic. In the past, DOI's regulatory flexibility analyses consisted of either a single sentence stating "no significant impact on a substantial number of small entities" or a recitation of the RFA compliance requirements with no accompanying analysis. During fiscal year 2000, some agencies within DOI exhibited improvement in RFA compliance, while others did not.

7. *National Association of Psychiatric Health Systems v. Shalala*, No. Civ.A. 99 – 2025 GK, 2000 WL 1677210, (D.D.C. Sept. 14, 2000).

Cooperation has been improving between Advocacy and some agencies within DOI on RFA matters. For example, the Minerals Management Service (MMS) continued to work with Advocacy to improve its RFA compliance, and held workshops for its regulators to learn more about RFA. Moreover, MMS has consulted with Advocacy about RFA issues in the rule drafting stage, and as a result, there has been some limited improvement in DOI's compliance. Others, such as the Bureau of Land Management (BLM), however, continue to be problematic.

Bureau of Land Management

Issue: Hardrock Mining. During fiscal year 2000, BLM has marginally improved its efforts in complying with the RFA. Advocacy continues to be concerned about its failure to consider fully the impact of its actions on small businesses and its failure to develop and analyze alternative regulatory solutions.

BLM's hardrock mining regulation of July 1991, which required miners to obtain a reclamation bond, was the subject of the *Northwest Mining v. Babbitt* case, where the federal District Court held that BLM failed to comply with the RFA.[8] The court found that BLM failed to use the proper size standard in its promulgation of the rule and remanded the rule to the agency.

In February 1999, BLM consulted with Advocacy about proposed size standards to be applied for the industry it regulates. BLM then used the agreed upon size standards in its revised proposal. However, the information provided in the economic analysis was inconsistent with, and did not support, the agency's certification of "no significant economic impact on small entities." Also, the agency did not consider meaningful alternatives to the proposal. The only alternatives considered by BLM were shifting mining operations to nonfederal lands, adopting different techniques, shortening the life of the mine, or temporarily halting mining until commodity prices increased. Each of these alternatives would have had significant adverse impacts on the industry and could not be considered reasonable options. In fact, BLM did not perform an economic analysis of these alternatives and did not consider alternatives that would mitigate BLM's proposed action.

The agency published the proposal for comment prior to the completion of a National Academy of Sciences (NAS) study. Congress ordered BLM to obtain the NAS study to determine the necessity of the regulation and identify possible alternatives. Advocacy suggested that BLM extend the comment period to allow the public a chance to review the NAS study prior to submitting comments, but BLM declined.

8. *Northwest Mining v. Babbitt*, 5 F. Supp. 2d 9 (D.D.C. 1998).

Subsequent to the closing of the comment period, Congress ordered BLM to provide at least 120 days for public comment on the NAS report concerning environmental and reclamation requirements relating to mining on public lands. On October 26, 1999, BLM published a supplemental proposed rule and reopened the comment period.

In February 2000, Advocacy submitted comments on the supplemental proposed rule. In its comments, Advocacy asserted that the supplemental proposal failed to cure the inadequacies found in the original proposal. BLM provided no insight into which, if any, of the NAS proposals it was considering, nor did it provide an economic analysis of the alternatives suggested by NAS. Advocacy argued that BLM must publish a new proposed rule for public comment if it was considering any of the NAS recommendations. Further, if BLM was considering finalizing the proposed rule, it must comply with the court's order and publish an adequate IRFA that addressed the inadequacies of the economic analysis contained in the proposal, including reasonable alternatives. Advocacy will continue to monitor any subsequent developments concerning this rule.

Issue: Millsite Rule. On August 27, 1999, BLM published a proposed rule in the *Federal Register* on locating, recording, and maintaining mining sites. In the proposal, BLM certified that the proposal would not have a significant economic impact on a substantial number of small entities.

Although BLM asserted that the changes were mere clarifications, Advocacy disagreed, insisting that the proposal would retroactively negate BLM practices that had been in effect for the last 20 years. For example, in the past there was no limitation on the number of millsites that a particular claimant could hold. The proposed "clarification" limited a claimant to no more than an aggregate of five acres of millsite land for each associated placer or lode mining claim. The penalty for having more than one five-acre claim, in the aggregate, is loss of any additional claims, including those claims that were established prior to the finalization of the proposed rule. Moreover, miners were previously allowed to correct errors in a mining claim or site location, even if the error was in excess of 10 percent. The proposal allowed miners to correct a defect in a mining claim or site location if it was oversized by 10 percent or less. If a miner exceeds its measurements by more than 10 percent, the claim or site is void as of the date that it was located.

The proposal also required a "metes and bounds" description for lode claims. However, such a description had never been required previously. Although the proposal stated

that the description did not require a professional surveyor or engineer, Advocacy argued that a miner would be foolish not to employ such an individual when faced with losing the entire claim for an inaccurate description.

Advocacy asserted that since the changes would likely result in harsh consequences resulting from minor errors and the invalidation of claims established in accordance with BLM's earlier longstanding practices, BLM failed to comply with the requirements of the RFA. More specifically, BLM used the wrong size standard. Instead of using the 500-employee standard that applies to mining operations, BLM used a $5 million revenue standard to determine which businesses were small. Moreover, the certification only referred to the imposition of fees. It completely ignored the issue of locating, recording, and maintaining mining claims and sites, as well as the retroactive application of the proposal.

Fish and Wildlife Service

The mission of DOI's Fish and Wildlife Service (FWS) is to conserve, protect, and enhance fish and wildlife and their habitats. To carry out its mission, FWS implements provisions of the Endangered Species Act (ESA), which includes designation of "critical habitat." Unlike declaring a species as endangered, in designating critical habitat the agency is required to consider the economic impact of that designation. If an area is designated as critical habitat, activities sponsored by federal agencies may not occur within the proposed critical habitat areas. By FWS' own admission, the "critical habitat" designation affects small entities that may have previously operated in the area through contract, grant, permit, or other federal authorization.

Advocacy is concerned with the agency's failure to provide the economic analysis at the time of the proposed rulemaking as required by both the RFA and the ESA. Because of an impending court deadline, Advocacy admittedly advised FWS that it could postpone the preparation of an economic analysis on one occasion. Unfortunately, FWS' failure to provide economic analyses appears to have become habitual. Instead of providing the RFA analysis while proposing a new regulation, FWS has simply stated that it will address the RFA issue at a later date and place a notification in the *Federal Register* concerning the availability of any analysis. FWS does not provide any timeframe for completion of the analysis or that it intends to comply with the publication aspect of the rule. This methodology does not comply with the spirit of RFA.

Department of Labor

The U.S. Department of Labor (DOL) has broad regulatory authority over wages, labor standards, and occupational safety concerns, including mine safety. The Pension and Welfare Benefits Administration (PWBA), Mine Safety and Health Administration (MSHA), and the Employment Standards Administration (ESA) are just some of the agencies within DOL which have drafted or promulgated rules in fiscal year 2000 with significant impacts on small businesses.

One agency in particular has a tremendous impact on small entities because of the scope of the regulations it promulgates. It is because of this potential regulatory burden that Congress mandated that the Occupational Safety and Health Administration (OSHA) follow special requirements under SBREFA when it considers regulations that will have a significant impact on small entities. The 1996 SBREFA amendments to the RFA established a new analytical process for both OSHA and the Environmental Protection Agency (EPA). The small business advocacy review panel process under SBREFA requires these two agencies to convene a special panel whenever the agencies cannot certify under the RFA that a regulatory proposal will not have a significant economic impact on a substantial number of small entities. To date, OSHA has convened three such panels.

Occupational Safety and Health Administration

During fiscal year 2000, Advocacy has continued to work with OSHA on various rules. One of the more significant rules, in terms of its potential impact upon small business, is the ergonomics program standard. The SBREFA panel on this regulatory proposal concluded in April 1999. After making some changes to the draft proposal, OSHA published a notice of proposed rulemaking on November 23, 1999. The comment period was extended a number of times; however it finally closed in March 2000.

Despite complaints from small businesses that the changes made by OSHA have not gone far enough to reduce the adverse impact of this proposal, Advocacy's experience in working on this and other panels has demonstrated that small business input early in the regulatory process improves the rule. None of the OSHA rules subjected to a SBREFA panel have been finalized. However, the SBREFA panel process itself (and the panel reports which were developed as a result of that process) have only added to the knowledge of the agency and its understanding of the realistic impact these rules may have on small entities. The time spent on these panels—and the subsequent work

with OSHA and OMB—has been and continues to be productive for both agencies and small businesses.

Issue: Ergonomics Standard. The purpose of the ergonomics standard is to reduce the number of repetitive stress disorders and other musculoskeletal injuries employees receive as a result of their regular work activity. The proposal covered every industry and business in the United States except those in construction, maritime, and agriculture. Twenty small entity representatives were chosen to advise the panel and provide input on the draft standard. The group included 13 owners or operators recommended by Advocacy to represent the interests of the many small businesses concerned about the potential impact of this rule.

Small businesses continue to have grave concerns regarding the proposed ergonomics standard published on November 23, 1999, especially with respect to the cost estimates. Most small businesses and their representatives previously indicated their disbelief in OSHA's estimation of the time and money the draft proposal would require for businesses to comply. OSHA did revise its initial cost estimates and provided some small business relief in the proposal. Written comments on the proposal provided OSHA with additional evidence that its cost estimates inaccurately reflected the impact on small businesses. Through panel suggestions and recommendations from Advocacy, OSHA provided the public with its cost and benefit assumptions in its proposed rule. This helped small businesses analyze the impact of the rule and assess the accuracy of OSHA's assumptions and conclusions.

Advocacy continued to work with interested businesses, trade associations, OSHA, and OMB to ensure that these and many other concerns of small business were heard and taken under consideration in preparation for the final rule. It is Advocacy's goal to assist the agency in accomplishing its public policy objective of a safe workplace, while avoiding an undue regulatory burden on small business. With this in mind, Advocacy will continue to follow the progress of OSHA's ergonomics standard and actively participate in its analysis and development on behalf of the millions of small businesses it will impact.[9]

Department of Transportation

The U.S. Department of Transportation (DOT) is the primary agency in the federal government with the responsibility for shaping and administering policies and programs

9. The final ergonomics standard was published in the *Federal Register* on November, 14, 2000.

to protect and enhance the safety, adequacy, and efficiency of the national transportation system and services. With public safety as an overall mission of many agencies within DOT, there is always a delicate balance in accomplishing the agency's important safety objectives without unduly burdening this nation's small businesses. DOT has made progress during the past year in recognizing the importance of considering small business effects when drafting regulations. However, more work needs to be done to ensure that these concerns are being addressed uniformly throughout the department.

During fiscal year 2000, DOT issued numerous regulations affecting small businesses, and the Office of Advocacy is happy to report that it maintained a more productive relationship with various DOT agencies regarding pre-proposal analysis of regulations. Slowly, some of the agencies are beginning to call Advocacy prior to submitting rules to OMB to inquire about the accuracy of their regulatory flexibility analysis and assumptions. Other agencies within DOT react positively to criticisms and suggestions on how their proposals can be amended to comply with the RFA.

Some of the more significant DOT rules reviewed by Advocacy this past fiscal year have been from the following agencies: the Federal Aviation Administration (FAA), the Federal Highway Administration (FHWA), the Federal Motor Carrier Safety Administration (FMCSA), the Federal Railroad Administration (FRA), the National Highway Traffic Safety Administration (NHTSA), the Research and Special Programs Administration (RSPA), and the U.S. Coast Guard.

Federal Aviation Administration

The FAA is responsible for air safety in the United States and promulgates many regulations to ensure the safety of the nation's skies. For the most part, the regulations attempt to address safety concerns that occur in some of the larger airlines. Admittedly, the FAA also directly regulates small business operations, i.e., air tour safety standards. However, the vast majority of regulations promulgated during the past year have been tailored for problems experienced by larger airline companies. As a consequence, Advocacy has heard from those small businesses that feel they are unduly burdened by "big airline" regulations, i.e., the "one-size-fits-all" syndrome. Advocacy continues to work with these businesses and the FAA to buttress the agency's compliance with the RFA. The FAA has made great strides in its analysis of the small business impacts of some of their rules this past year. However, more work needs to be done. Advocacy will continue its positive working relationship with the FAA as the agencies both strive to minimize the adverse impact of such regulations on those small businesses in the industry.

Issue: Emergency Medical Equipment. On May 24, 2000, the FAA published a proposed rule regulating the use of emergency medical equipment onboard aircraft. The proposal required operators to obtain and train their employees on the use of defibrillators in case of a medical emergency necessitating their use. Advocacy recognized the extremely important passenger safety goal that the FAA was addressing through this proposed rule in response to a congressional mandate. However, in an effort to ensure that the rule was in compliance with the RFA, an adequate analysis of the rule's impact on small business was required.

Within the proposal, the FAA certified that the rule would not have a significant economic impact on a substantial number of small entities and completed an economic analysis to support its conclusion. On September 21, 2000, Advocacy filed comments on the proposed rulemaking, asking the FAA to review its certification statement under the RFA and to make additional information available to the public. Specifically, Advocacy questioned FAA's estimation of the number of small operators that would be affected by this rule. Without a listing of the data sources in the proposal, it was difficult to confirm FAA's estimate. More important, the FAA's certification of no significant small business impact appeared to be based upon data from the large operators. Advocacy urged the FAA to comply with the RFA by providing the information necessary for the public to assess the accuracy of its projected impact on small operators. The Office of Advocacy will work closely with the FAA to assist them in the next stages of this rule's development.

Issue: Grand Canyon National Park. The FAA has proposed a rule that assigns special flight rules and limits the number of flights for small air tour operations over the Grand Canyon National Park. Advocacy has been closely involved with this rulemaking throughout its progress over the last five years. On July 9, 1999, FAA published a notice of proposed rulemaking on this issue. In December 1999, Advocacy worked closely with the Office of Information and Regulatory Affairs (OIRA) at OMB. Advocacy took part in meetings on this proposed rule and discussed the various concerns voiced by small business. Advocacy has encouraged FAA to review its economic impact analysis, specifically the choice of the base year used to estimate the impact. Advocacy also urged the FAA to comply with the RFA by identifying and analyzing any reasonable alternatives to the proposal that would minimize any significant economic impact on small entities. Advocacy will continue to be concerned about regulations that, among other things, limit small business entry into the marketplace.

Federal Motor Carrier Safety Administration

The FMCSA was established within DOT on January 1, 2000, pursuant to the Motor Carrier Safety Improvement Act of 1999. Formerly part of FHWA, the FMCSA's primary mission is to prevent commercial motor vehicle-related fatalities and injuries.

Issue: Hours of Service of Drivers. On May 2, 2000, FMCSA published a proposed rulemaking revising its hours of service regulations for drivers of motor carriers. FMCSA issued this proposal in order to require motor carriers to provide drivers with better opportunities to sleep, and thereby reduce the risk of drivers operating commercial motor vehicles while drowsy, tired, or fatigued, with the objective of reducing collisions. In addition to a change in the actual number of hours drivers are allowed to operate their motor carrier, the proposed rule mandates the purchase and use of costly electronic on-board recording devices.

Prior to publication of the proposal, the Office of Advocacy held meetings and discussions with FMCSA in order to bring them into compliance with the RFA. Advocacy worked closely with the agency to ensure that the proposal published on May 2, 2000, would be informative and useful for small businesses in their analysis of the impact of the rule.

Since the rule was proposed by FMCSA, Advocacy has responded to numerous requests for participation in meetings, roundtables and discussions regarding this rule. Small motor carrier operators have indicated that the rule would have a devastating impact on them. Industry has stated that the rule would necessitate more than 40,000 new truck drivers on the road. Small business complaints focus on the sleeper berth requirements, communications during rest periods, end of workweek rest periods, hours of work permitted each day, and the mandatory purchase and use of an electronic on-board recording device.

Advocacy attended numerous meetings on the proposal at OMB and also with industry. A congressional hearing was held to discuss the severity of the impact of the proposal on the industry as a whole. Small business concerns under the RFA also were discussed at this hearing. After a number of comment deadline extensions, FMCSA set the deadline for comments for December 15, 2000. Advocacy will continue to work with both the agency and OMB on this important rule and will attempt to ensure FMCSA's compliance with the RFA.

Department of the Treasury

The mission of the U.S. Department of the Treasury (Treasury) is to promote prosperous and stable American and world economies and manage the federal government's finances while safeguarding its financial systems. Accordingly, Treasury performs four basic functions: (1) formulating and recommending economic, financial, tax, and fiscal policies; (2) serving as financial agency for the United States Government; (3) enforcing law related to these areas; and (4) manufacturing coins and currency. Of these responsibilities, formulating and recommending tax policy and enforcing tax law have the most dramatic impact on every business, large or small. In addition to the Internal Revenue Service (IRS), other divisions, such as the Bureau of Alcohol, Tobacco, and Firearms (ATF) and the Office of Thrift Supervision (OTS) also have an impact on the operation of some small businesses.

Bureau of Alcohol, Tobacco and Firearms

ATF is a law enforcement organization within Treasury with responsibilities dedicated to reducing violent crime, collecting revenue, and protecting the public. ATF enforces federal laws and regulations relating to alcohol, tobacco, firearms, explosives and arson. During fiscal year 2000 Advocacy has reviewed a number of regulations promulgated by ATF. Some of the significant rules are discussed below.

Issue: Aggregated Packing. February 9, 1999, ATF filed a proposed rule seeking to regulate alcohol that is packaged together but can be broken out individually from packaging. For example, a package of 16 one-ounce test tubes containing alcohol product may be wrapped together and sold as a pint. This kind of packaging previously had the approval of the ATF. However, Advocacy believed that the proposed rulemaking would force some small companies to go out of business. ATF, in its certification on the rule, said the following:

> This proposal *strengthens existing regulations* that prohibit the use of unauthorized container sizes and that protect consumers from being misled about the identity, quality or quantity of the product. ATF believes that because this proposal addresses only deceptive or confusing packaging, and not the products themselves, it will not burden sales or otherwise impose costs on distributions or retailers of alcoholic beverage products, Accordingly, ATF certifies this proposed rule will not have a significant impact on a substantial number of small entities. Therefore, ATF is not required to conduct an initial regulatory flexibility analysis.[10]

Advocacy heard from business owners and their representatives about the potential damage that the rule could cause for small businesses. The businesses argued that a

10. 64 *Fed. Reg.* 26, 6488.

significant number of packagers (and the brokers, dealers and suppliers who do business with these packagers) would suffer a substantial impact as a direct result of this proposed regulation. Some of the packagers have received prior approval from the ATF to market and sell its products using distinctive packaging that might now be prohibited. They relied on this approval as assurance that they were in compliance with the law and existing regulations. The businesses made significant business investments. The businesses read the proposed regulations and concluded that compliance would require a fundamental and expensive change in their businesses.

Advocacy filed comments on November 16, 1999, and indicated to the ATF that the rule had the potential to have a significant impact on a number of small businesses, and that it required a thorough analysis. It was Advocacy's position that the rule did more than simply strengthen the existing regulations; it prohibited several forms of packaging that ATF had previously approved. Advocacy has yet to hear from the ATF about its position on this matter. Advocacy will continue to monitor all further developments.

Internal Revenue Service

Under the 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 escaped the requirements of the RFA because it categorized most of its rules as "interpretative"—meaning the rules simply carry out the intent of Congress and do not impose any additional requirements. In 1996, SBREFA amended the RFA to require that interpretative rules, including internal revenue laws, that impose a collection of information requirement on small entities would be subject to the RFA.

Since passage of SBREFA, the IRS has worked with Advocacy to learn more about complying with the RFA. The IRS is publishing more certifications and has done IRFAs with more frequency. In fiscal year 2000, the IRS was responsive to Advocacy's requests for meetings with concerned small business groups to discuss high-visibility and/or controversial rules. Additionally, the IRS requested suggestions from small businesses about which problems were the most onerous, and input on the best approach to solve such problems before the publication of regulations, technical advice memoranda, or guidance advisories.

The IRS is providing more information in support of its certifications that a rule will have "no significant impact on a substantial number of small entities." Advocacy

believes, however, that the IRS could provide even more factual justification for some rules. For example, it would be helpful to know the number of businesses that will be affected and the costs of recordkeeping, beyond just the length of time it takes to fill out a form.

Advocacy is encouraged by the increasing awareness of RFA responsibilities by Treasury and the IRS. In some cases, the effort they have made to justify regulatory action, while avoiding RFA compliance, has previously resulted in creating a miniature panel-like process similar to the one that SBREFA amendments to the RFA requires of OSHA and EPA. In those instances, Advocacy cannot help but believe the effort has led to better rulemaking. Treasury has opposed congressional proposals to extend the SBREFA panel review process to IRS regulations. Yet the outreach by Treasury and the IRS to small businesses has been commendable. They have done an excellent job of listening to small business concerns and acting on them. This is particularly true for the Treasury's Office of Tax Policy, Employee Benefits Division, that regulates pension plans. In a number of cases, they have consulted with Advocacy and other small business groups in an effort to anticipate problems in the pre-proposal stage and incorporate what they learn into their rulemaking.

Issue: Most IRS Regulations Are Not Analyzed. It should be noted that the vast majority of the IRS regulations published in fiscal year 2000 were not subject to the RFA, even though SBREFA extended application of the RFA to "interpretative rules" that impose a collection of information requirement. The following are examples of the types of IRS regulations that do not require analysis:

- The RFA applies only to "legislative" regulations. The IRS has always maintained that virtually all its regulations are interpretative and therefore exempt from the RFA. Such regulations simply clarify definitions or provide examples of application of requirements that were set by Congress, the IRS maintains.

- Most IRS regulations have an impact on groups other than small businesses, such as individuals or large businesses; these are not covered by the RFA.

- Any interpretative regulation that was proposed prior to March 29, 1996, is not subject to the RFA even as amended by SBREFA.

Since IRS regulations that impose recordkeeping requirements have been subject to the

RFA only since 1996, IRS maintains it is not required to form a plan under RFA section 610 to review regulations they were not required to analyze in the first place. Advocacy believes that it would be useful to coordinate the feedback IRS is getting from the small business community on overly burdensome or confusing rules with a routine review process. The "Complexity Conference," held in conjunction with the OIRA during the summer of 2000 is an excellent start in that direction.

Issue: Rulemakings that would Benefit from Analyses. In some instances, the IRS has made the conscious decision not to perform an IRFA. In certain kinds of situations, Advocacy has argued that an IRFA drafted by the IRS and shared with the persons to be regulated would create better understanding and better policy. For example:

- Even when a rule imposes a collection of information requirement, 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. Advocacy believes that once the IRS has undertaken a review of the regulation, it should analyze how the entire regulation will affect small business. The regulator needs to know the whole impact on the regulated entity to properly assess any additional difficulty that the collection of information adds to the entity's ability to comply with the rule.

- The IRS has often taken the view that unless a form is required (literally, a paper document that a taxpayer must complete) there is no recordkeeping requirement imposed by the rule. In cases where a proposed regulation would add a line or a section to an existing form, the change is generally deemed to be insignificant by the IRS, and therefore not a new "collection of information" requirement for RFA purposes. Advocacy believes that much more information gathering and effort goes into the form completion process than this policy acknowledges. Additions to the form add cumulatively to the burden and Advocacy believes it is fair for the entire burden to be reviewed and presented by the IRS. If the regulatory process works properly, then this new step would not create additional work. The regulator is charged with reviewing the entire burden in any event to make an informed decision as to whether the collection of information is significant.

- The IRS occasionally alleges that a proposed regulation in an entirely new area will have a significant impact on a substantial number of small businesses, but that its requirements simply and specifically "flow from mandates set by Congress."

Advocacy understands that directives from Congress may preclude any alternatives. However, in Advocacy's opinion an analysis needs to be done where there is a significant impact on a substantial number of small businesses. The analysis serves to alert the small businesses of the substance of the regulation so that they can prepare for compliance. Small entities might also be able to suggest useful alternatives for compliance. The analysis may serve to inform the legislative and administrative policymakers of the true burden that their decisions impose on small businesses.

Issue: IRS Restructuring and Reform Act. Since the plans for the restructuring of the IRS were announced, and with the passage of the IRS Restructuring and Reform Act of 1998, the IRS has undertaken a massive project to reshape the agency. One of these units is the Small Business and Self-Employed Operating (SB/SE) Division, which will serve the millions of taxpayers that are small businesses. The IRS recognizes that these taxpayers often face complicated tax issues, but may lack the financial resources to understand and address the issues. One of the primary focuses of the SB/SE Division will be to educate small businesses about their federal tax responsibilities and to work with them to develop less burdensome and more practical means of compliance. The new SB/SE division is in place and commencing operations.

The IRS restructuring process involved many administrative changes that have an impact on small businesses. Advocacy and countless other small business stakeholders have been involved in a continuing process of briefings and comments on the proposed structure and guidelines. The IRS sought Advocacy's opinions, and the opinions of small businesses recruited by Advocacy, to help IRS analyze its future plans. Although the effort expended by the IRS is not exactly a regulatory activity per se, the restructuring involves changes in the culture of the IRS that will make it more sensitive to the needs of small business. The IRS Restructuring and Reform Act of 1998 itself sets out small business requirements. For example:

- The act suggests that the IRS create a customer-friendly attitude and a division for small business. Advocacy has long advocated and supported this proposition. IRS has taken steps to implement this goal.

- The act creates an oversight board for the IRS that includes someone experienced in running a small business. The board has now been formed.

- In consultation with Advocacy, the small business division established a size standard that was suitable for determining which businesses will receive the specialized attention of the small business division.

- The IRS consulted with Advocacy on the manner of referrals between taxpayer education divisions and compliance divisions as well as other outreach elements (such as the Taxpayer Advocate).

Issue: IRS Outreach Programs. As part of its restructuring, the IRS has embarked on an ambitious program of outreach. The program is designed to unearth and report on regulatory problems. Other efforts are primarily focused on educating small businesses about their rights and the current legal and regulatory requirements for their businesses. The following describes some of the more pertinent outreach efforts made by the IRS during 2000.

- *Small Business CD-ROM*. The IRS is exploring new ways to communicate with small businesses, including the use of CD-ROM and the Internet. The IRS and the Small Business Administration jointly prepared a CD-ROM entitled *Small Business Resource Guide: What You Need To Know about Taxes and Other Topics*. This research tool is organized by the stages of a business's life cycle and includes small business tax forms, publications and explanations about what the law and regulations require from small businesses.

- *IRS Web Page and Regulatory Information*. The IRS Web Page contains a number of searchable regulation sections as well as a section with a "plain English" description of all regulations proposed and issued since 1995. Additionally, the IRS now includes a section entitled, "The Small Business Corner." It provides small business taxpayers with the information necessary to comply with their federal tax responsibilities. Finally, the *IRS Bulletin* publishes rules and regulations of interest to small businesses and the latest action taken on regulatory efforts.

- *OIRA and IRS Conference on Regulatory Complexity and Simplification*. During the spring and summer of 2000, the IRS and OIRA hosted a series of meetings with small businesses and other interested groups in an effort to create an agenda of regulatory issues that need to be addressed by the federal government. Attending the conference were hundreds of small business owners from across the country that helped set an agenda for future federal action.

- *Tax Form Forums*. The IRS has held two tax form forums to actively solicit broad-based feedback about form complexity and ideas to relieve the burdens associated with the forms. The IRS held a series of professional and business roundtables that reviewed in detail tax form problem issues.

- *IRS—Small Business Development Center Memorandum*. In an effort to provide education and materials to small businesses outside the sometimes threatening office of the IRS, the Commissioner of the IRS signed an agreement that provides training assistance information materials for distribution by SBDCs and small business investment companies (SBICs). Advocacy joined this effort by training SBDC operators on how to pass along regulatory or policy complaints to Advocacy and/or the Regulatory Fairness Ombudsman for action.

Issue: Simplified Tax and Wage Reporting System. During fiscal year 2000, Advocacy continued to work with the IRS to establish one simple form that would satisfy the wage and tax reporting obligations of the very smallest businesses under both federal and state tax law. The overall program is called State Tax and Wage Reporting System, or STAWRS. Advocacy feels that the most important part of the system aims at burden reduction for small businesses. Each project could significantly reduce the paperwork burden and compliance costs for business owners through the following mechanisms:

- *Single-Point Filing*: 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 and wage reporting is a costly burden for small businesses.[11] The solution would be to create a simple, multi-purpose form that eliminates 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 filng." Started in Montana during fiscal year 1999, the program has successfully provided one form of treatment for participating small businesses. The template used in Montana was duplicated and computerized to establish the electronic "single-point filing" project conducted in Iowa that in turn has led to breakthroughs in electronic filing.

- *Commercial Off-the-Shelf Single Point Electronic Filing*: This year the STAWRS program has moved forward to establish the rules and framework for the electronic

11. See *The Changing Burden of Regulation, Paperwork and Tax Compliance: A Report to Congress* (SBA Advocacy 1995)

filing of multiple-employer-related documents. The concept of the plan is to use one "template" document that would provide any requisite information to each state, federal, and local agency. Advocacy has worked with the executive board to decide the standards to be used for the project and to make sure that the small business point of view is not lost. The pilot project in Iowa went well and the IRS is now moving forward to establish networks of state government partners and commercial computer service providers to bring the program online nationally.

Issue: Employee Benefits Working Group and Pension Plans. The Employee Benefits Working Group at Treasury has made a special effort to respond to the small business community. During the last year, Advocacy worked with this group in an effort to resolve two major areas: more flexibility for small business 401(k) plans and comparability testing for defined contribution plans and benefits.

- *401(k) Flexibility*. Advocacy established a regular working group with Treasury and IRS officials to bring to their attention minor problems that Advocacy believed could be solved by regulatory action rather than legislation. During these meetings, held during fiscal years 1999 and 2000, Advocacy presented a list of problematic items and involved small business experts in pension issues. Treasury, through its Office of Tax Policy, Employee Benefits Division, joined the meetings and used the sessions to determine issues ripe for action. For example, Advocacy and these groups reviewed the 401(k) safe-harbor plans. These are simplified pension plans established by Congress to give small businesses the opportunity to establish meaningful pensions for their employees within reasonable limits and without cumbersome formulas and complicated antidiscrimination tests. One problem faced by small businesses was that they had to commit to a participation level early in the tax year to be eligible for the plan. For many small businesses this is a serious problem, since they sometimes do not know if they will turn a profit until the last quarter of their tax year. As a result, small businesses might be afraid to take on the extra financial obligation at the beginning of the year. The Office of Tax Policy worked with the IRS to establish a procedure to allow small businesses to wait until November of the tax year to announce contribution levels.

- *New comparability testing.* Comparability testing allows the age and service of employees to be considered in a formula that sets benefit levels. Because abuses had been reported, the IRS and Treasury intended to strengthen regulations to pre-

vent abuse. As they began to consider drafting such regulations, questions arose concerning how far the regulations should go and the scope of the problem. Treasury and the IRS contacted Advocacy and asked that it alert small business pension experts that Treasury was preparing a rule in the area of comparability testing. A meeting was held to elicit the views of these experts on the effects of such a rule. All this was done before any proposal was made. Throughout fiscal year 2000, the working group met with Treasury to provide additional background and information about what standards should be set for the controversial plan on comparability testing.

Treasury issued a notice announcing that it would propose a comparability rule and it requested general pre-rule comments from the public. Treasury also followed the advice of the working group and stated that any rule promulgated would not take effect before 2002. This delay served to reassure the pension and small business community and gave them sufficient time to adjust their markets to the anticipated regulation. The proposed regulation, incorporating the changes recommended by the working group, was published October 6, 2000.

Issue: Cash versus Accrual Accounting and Business Inventory. These two important small business issues collided with each other this past year. Advocacy worked throughout 1999 and into 2000 to encourage the IRS to liberalize the rules that would allow small businesses to use cash accounts for tax purposes. It appeared that IRS field officers were imposing accrual accounting requirements on far more small businesses than was required by law. The law requires large businesses to use accrual accounting (the recognition of income and expenses when the obligation for them occurs), rather than cash accounting (the reporting of income or expense when the cash is actually received or distributed). However, where a business has an inventory, the law requires accrual accounting. Advocacy felt that very small businesses (even ones with some inventory) should be able to use cash accounting if they so choose because it reflects their true income. Advocacy opined that the extra burden of accrual accounting is not warranted in such a circumstance.

Advocacy and other trade associations formed a working group with the IRS on the issue. They reviewed, with IRS key officers, existing IRS policy and its impact on small business. The IRS agreed to review the policy and issue guidance that would make it clear that raw materials that were not a substantial part of the business of the

taxpayer would not qualify as inventory. Therefore, the IRS would not impose accrual accounting in those instances.

Issue: Cash versus Accrual Accounting and Installment Sales Accounting. On December 17, 1999, a new law was enacted that prohibited the use of the installment method of reporting income from the sale of assets (spreading the attributable income over a period of years) in cases when a business must use the accrual method of accounting. This meant that when a small business that uses accrual accounting is sold and the owner takes back a note, the gain from the sale must all be reported in the year of the sale, even though proceeds from the sale might not yet have been received by the owner. For many small businesses, the business itself is the only retirement savings account the owner has. Clearly, the sale of all the assets is much different than a sale of some assets. If the owner cannot take back paper, the price of the business is reduced in value.

Working with the IRS and a number of other small business groups, the IRS and Treasury were willing to issue guidance that created a $1 million gross receipt threshold. Businesses below that level could simply choose cash or accrual accounting. Above that level, the IRS and Treasury felt that only Congress could change the standard. Advocacy disagrees with the position espoused by the IRS and Treasury, but supports legislation on the issue in Congress.

The Office of Thrift Supervision

The Office of Thrift Supervision (OTS) was established as a bureau within Treasury in 1989. As the primary regulator of all federal and many state-chartered thrift institutions, OTS' mission is to supervise thrift institutions to maintain their safety and soundness in a manner that encourages a competitive industry that meets the nation's housing, community credit and financial service needs.

During fiscal year 2000, OTS engaged in several important rulemakings in response to the passage of the Financial Services Modernization Act of 1999 (the Gramm-Leach-Bliley Act). OTS requested Advocacy's assistance on some of these proposed regulations, which, pursuant to the Gramm-Leach-Bliley Act, required "fast-track" implementation within six months. OTS performed IRFAs on the rulemakings that were reviewed and commented on by Advocacy.

Issue: Insurance Customer Protection. The Gramm-Leach-Bliley Act regulations reviewed by Advocacy included a rule addressing insurance customer protection. This

proposed rule applies to savings associations and any other person who, at, or on behalf of a savings association sells, solicits, advertises, or offers insurance products or annuities to consumers. The rule proposes new disclosure and consumer acknowledgement requirements. It prohibits coercion, lying, misrepresentations, and domestic violence discrimination. The rule requires separation of deposit activities from insurance and annuity activities, limits referral fees, and requires that insurance and annuity sales personnel be appropriately qualified and licensed. In order to lessen the compliance burdens on small entities, the OTS proposal narrowed the types of entities regulated and the definition of the activities covered by the rule.

Advocacy also reviewed a set of privacy regulations for financial institutions that the OTS implemented in conjunction with several other financial agencies such as the Office of the Comptroller of the Currency (OCC), the Federal Reserve System (FRS), and the Federal Deposit Insurance Corporation (FDIC). The proposed standards are intended to ensure the security and confidentiality of customer records and information; protect against any anticipated threats or hazards to the security or integrity of such records; and protect against unauthorized access to or use of such records and information that could result in substantial harm or inconvenience to any customer. In its IRFA, the OTS considered several alternatives to the extent that they were consistent with the congressional mandates of the Gramm-Leach-Bliley Act.

During the year, Advocacy also provided guidance on IRFAs prepared by OTS for its proposed amendments to regulations concerning mutual to stock conversions; and OTS' regulatory proposal to require certain holding companies to notify it before engaging in certain activities and transactions.

Environmental Protection Agency

The U.S. Environmental Protection Agency (EPA) has taken its responsibilities under the RFA seriously since the law's enactment in 1980. EPA's successes in this regard are not surprising, however, since several principles underlying the RFA were developed from an examination of EPA's regulatory work. Further, some provisions of SBREFA were also modeled after EPA programs. Although there remains a wide variance in RFA compliance in individual EPA rulemakings, the agency has historically received high marks from Advocacy for its overall efforts.

During fiscal year 2000, Advocacy continued to be heavily involved in pre-proposal activity with EPA. This activity has increased since the passage of SBREFA in 1996, which required EPA and OSHA to acquire very extensive pre-proposal input from affected small entities and engage in the panel process discussed in the OSHA section of this report. Listed below are five particularly significant rulemakings where Advocacy played an important role. Four of the rulemakings involved a SBREFA panel. Of the four rules that required a panel proceeding, only one rule has been promulgated to date—the transportation equipment cleaning water pollution rule.

Issue: Secondary Aluminum Industry Obtains Regulatory Relief. Aluminum die casters and aluminum foundries will save an estimated $20 million annually, thanks to the efforts of Advocacy that helped to alleviate the effects of regulations promulgated by EPA. Advocacy worked closely with two industry trade associations, the American Foundry Society and the North American Die Casters Association. Advocacy objected to the inclusion of the two industries in a draft final rule issued by the EPA, which was published in the *Federal Register* on February 11, 1999. The rule was issued to reduce hazardous air pollutants from a much larger industry grouping, secondary aluminum production plants.

Secondary aluminum production plants recover smelt aluminum from new and used scrap, such as beverage cans, foundry returns, and other aluminum scrap. The rule was issued pursuant to the Clean Air Act of 1990, which required the EPA to list and promulgate standards for seven specific air pollutants, including dioxin and furans. Secondary aluminum production plants were previously identified by the EPA as an industry group known to be a "source category" of dioxin and furans. According to EPA, there are more than 400 traditional secondary aluminum production plants in the United States, of which some 86 facilities are believed to be major sources of air toxics per the EPA. In addition, the EPA estimates that there are some 1,650 aluminum extruding, die casting, and foundry facilities that are "potential" sources of dioxin and furans in the United States.

Considering the potentially large costs that the two industries would have to bear should the proposed rule be implemented, Advocacy argued that the EPA lacked sufficient evidence of dioxin and furan emissions to include the aluminum die casting and foundry industries in the proposed rule. After reviewing Advocacy's comments on the rule, the EPA determined that it would gather further information concerning these two

industries in an effort to reevaluate the air toxics requirements and associated economic impacts on the two industries.

Advocacy has learned that within two years, the EPA expects to adopt an alternative standard applicable to these industries, and to take final action to remove both industries from the current standard that was finalized on December 15, 1999.

Issue: Flexible EPA Regulation Will Save Truck Cleaning Industry Millions. After substantial input from Advocacy and the transportation equipment cleaning industry, the EPA has promulgated a water pollution rule that will save hundreds of facilities millions of dollars in annual costs. The final rule offers facilities that generate wastewater in cleaning trucks and containers two options in meeting pollution standards: numerical limits or pollution prevention. The National Tank Truck Carriers (NTTC), an industry trade group, expects that most of its members will employ the pollution prevention methods at substantial savings over the traditional approach. The input of Advocacy and of the industry in crafting the final rule represents another success for SBREFA.

Industry specialists estimated that the initial capital costs of the original proposed rule would exceed $80 million and that the rule would trigger approximately $13 million in additional annual operating costs for the tank truck cleaning industry.

In 1997, EPA, OMB, and Advocacy convened a panel to review the proposed rule to regulate the wastewater generated by facilities that clean tank trucks and containers transporting products. The tank truck cleaning industry was predominately affected.

Advocacy worked with industry representatives to recommend ways to reduce the costs of the rule without damaging the environment. These original recommendations included exempting subcategories of facilities that caused minimal pollution to the water and totally exempting drums used for transporting products. Advocacy pointed out that EPA overestimated the amount of pollution caused by the facilities, because the estimates were based on pollutants caused by pesticides that had long since been banned in the United States. Therefore, in the panel report, Advocacy asked the agency to re-evaluate how much the draft regulation would reduce water pollution.

In July 1998, the EPA published a proposed rulemaking requiring facilities to use expensive technology to treat the interior wastewater generated in the cleaning of tank trucks transporting petroleum products, food grade products, and chemicals.

The proposed regulation affected primarily "indirect dischargers," those facilities generating wastewater sent out to be treated by publicly owned treatment works before being released into U.S. waters. Accepting the panel report's earlier recommendation, the proposed regulation did exempt all drums. However, both Advocacy and the NTTC believed that because the proposed rule was based on incorrect pollution estimates, the regulation for the tank truck subcategory was overly stringent.

The final rule was published in July 2000. Based on substantial industry and Advocacy input, the EPA revised its benefit estimates, dropping those based on removing pesticides that had already been banned. After the revisions, the EPA found the regulation of the truck-chemical subcategory to be one of the least cost-effective effluent guidelines in recent history. Based on advice from Advocacy and the NTTC, the agency decided to offer two options: numerical pollution limits or a possibly less costly pollution prevention approach. Advocacy, with industry input, helped develop a methodology for analyses by EPA that is widely recognized as a model for evaluating future effluent guidelines.

Issue: The Metals Products and Machinery SBREFA Panel. In March 2000, EPA completed a panel regulating the discharge of water pollutants from the facilities that manufacture metal products and machinery. This is a very important rulemaking, which is expected to cost approximately $1 billion annually. Since EPA estimates that the rule would affect about 10.000 facilities, at significant cost, this was a very important SBREFA panel. EPA staff spent substantial time planning and gathering data for the panel before it was convened, including consultation with representatives from the affected small entities many months before the start of the panel process. This methodology demonstrated the proposition that early planning and fully informed data and analysis are the crucial ingredients for a successful panel.

The panel was given detailed data about the various industrial subcategories that could be subject to regulation. This permitted the panel to formulate specific recommendations to either eliminate industrial categories from the national regulations (local regulations would still be applicable), or reduce the stringency of some of the remaining regulated categories. The federal panel members were generally unanimous on all issues, which is another sign of a successful panel process. The proposed rule is scheduled for publication in December 2000. Industry representatives are expected to work closely with EPA staff analyzing the data during the four-month comment period.

Advocacy estimates that implementation of the panel recommendations in a final rule would save hundreds of millions of dollars annually.

Issue: Concentrated Animal Feedlots SBREFA Panel. In a panel completed in April 2000, Advocacy considered a rule which expands and revises Clean Water Act regulations that define which operations are concentrated animal feeding operations (CAFOs) and establish permit requirements and technology-based water pollution standards for CAFOs. These are operations that confine and feed beef cows, dairy cows, pigs, turkeys or chickens over certain periods of time. EPA is concerned that CAFOs might discharge pollutants into U.S. waters.

During the panel, Advocacy worked closely with an unusually large number of small business representatives, representing a wide range of operations, perspectives, and interests, in an effort to help evaluate regulatory options under consideration by the EPA. The goal was to update and improve existing CAFO rules. Advocacy was successful in persuading the EPA to consider a number of ways to restructure the options to help increase flexibility for smaller operations without compromising the Clean Water Act's objectives. Based on available data, Advocacy estimates that just one of these "flexibilities" will help to save $2-$15 million per year. Advocacy also persuaded EPA to collect additional data and perform additional analysis to help inform discussions of rule changes under consideration as the rulemaking process continues. The proposal is scheduled for December 2000.

Issue: Reinforced Plastic Composites Industry SBREFA Panel. In June 2000, EPA completed a panel involving an air pollution standard for the reinforced plastic composites industry. The reinforced plastic composites manufacturing industry would save an estimated $68 million annually as the result of the efforts by the EPA and Advocacy and would serve to reduce the impacts of draft Clean Air Act regulation of hazardous air pollutants (HAPs) under development by EPA. The regulations will result in national emission standards for HAPs for the industry that are to be based on the application of air pollution reduction measures known as maximum achievable control technology (MACT). The reinforced plastic composites manufacturing industry manufactures a wide range of products containing reinforced plastic composite materials, including shower enclosures, hot tub spa shells, pickup truck caps, recreational vehicle body panels, helmets, and storage tanks. There are several hundred identified facilities in this source category that are believed to be major sources subject to the regulation and are small businesses.

EPA considered MACT standards for existing facilities in the reinforced plastic composites industry that would include pollution prevention measures to reduce emissions of HAPs. For larger new and existing facilities, the MACT standard would require add-on controls, such as incinerators, to reduce emissions. As part of the panel review process, several regulatory flexibility provisions were evaluated with the aim of reducing regulatory burdens for small entities.

During the panel, Advocacy consulted with the industry and its primary trade association, the Composites Fabricators Association (CFA). Advocacy and the industry identified to the panel several objectionable provisions concerning the proposed standards for existing and new sources in several subcategories. The provisions at issue would be technically difficult and economically costly for the industry to achieve. Advocacy worked closely with the industry representatives and CFA to develop proposed alternate approaches for reducing the costs of the rule without compromising the environmental objectives of the rule.

The panel report made several recommendations that would provide significant relief to small businesses in the industry. Among these recommendations were the adoption of standards that are more closely tailored to several subcategories of products in the industry and other flexible standards for the affected small businesses.

Federal Communications Commission

The U.S. Federal Communications Commission (FCC) is an independent agency that was established in 1934 to regulate interstate and international communications by radio, television, wire, satellite, and cable. In 1996, Congress passed the Telecommunications Act of 1996 to increase competition in communications. This law imposes upon the FCC the obligation to disseminate communications licenses among a wide variety of applicants, including minorities, women, and small business. The new law also established the Telecommunications Development Fund to promote small business access to capital and to enhance competition. The fund stimulates development of new technology and promotes delivery of communications services to underserved areas. Some proceeds from FCC spectrum auctions contribute to this fund.

Issue: Wireless Medical Telemetry Devices. In July 1999, the FCC proposed creating a new service for wireless medical telemetry devices (e.g. heart monitors) to protect

them from harmful interference. Advocacy filed comments on October 18, 1999, indicating that the FCC failed to study the rules' impact on small business and failed to propose alternatives designed to lessen this impact, consistent with FCC regulatory goals. On June 8, 2000, the FCC issued final rules in this proceeding. The FCC's regulatory flexibility analysis again failed to identify small business impact. The FCC defended its RFA compliance by asserting that it applied the same standards to businesses of all sizes. Advocacy filed a letter on August 28, 2000, highlighting the agency's continued deficiencies and emphasizing that the RFA was intended to eliminate "one-size-fits-all" regulation.

Issue: Spread Spectrum Devices. In July 1999, the FCC proposed rules to widen the bandwidth available to spread spectrum devices and to modify spectrum interference testing. Advocacy filed comments indicating that the FCC failed to describe the impact the rules would have on small business. The FCC issued final rules on August 22, 2000.

Issue: Extending Wireless Services to Tribal Lands. In August 1999, the FCC proposed changing technical rules governing wireless services in order to increase the cost-effectiveness of building out wireless systems to tribal lands and other sparsely populated areas underserved by traditional telephone services. One proposal would lift restrictions on transfer of PCS C-Block licenses to non-small businesses and would base future bidding credits on commitment to serve a community, not on business size.

Advocacy opposed this proposal, in comments dated November 9, 1999, and rejected the FCC's apparent premise that large businesses are more likely than small businesses to devote the necessary resources to serving underserved and tribal lands. The FCC also devoted inadequate discussion to the impact of its proposal on small businesses and failed to propose alternatives designed to minimize this impact. The FCC has taken some action, but final action is pending.

Issue: Local Competition and Broadband Reporting. In late October 1999, the FCC tentatively decided to collect information regarding local competition and broadband deployment from all local telephone service providers. The FCC estimated the compliance burden at 30 or more hours per report, which would be filed quarterly. The FCC would create an exemption for those carriers with fewer than 50,000 access lines. However, this exemption would be waived if the carrier provides more than 1,000 broadband lines.

Advocacy filed comments on the rule in late December 1999. Advocacy commended the FCC's efforts to balance its need for information on the status of local competition and broadband deployment with the burdens imposed on small businesses. Advocacy recommended that the FCC allow voluntary surveys or adopt a short form for small businesses. Advocacy also recommended the report be filed annually and all information be collected on a statewide basis, and that the broadband exemption threshold be placed at least at 5,000 broadband lines. Finally, Advocacy asked that the FCC provide a description in the FRFA detailing what information the FCC is collecting, its need for the specific information collected, and how the FCC intends to use the information collected in later rulemakings.

In its Report and Order, the FCC adopted none of Advocacy's recommendations. Instead, it decided to collect information on local competition and broadband deployment on a semi-annual basis and to exempt small businesses with less than 10,000 access lines or 250 broadband lines per state.

Issue: Digital Audio Broadcasting. In November 1999, the FCC issued a notice of inquiry exploring technical standards for digital audio broadcasting technology. On November 24, 1999, Advocacy urged the FCC to wait for real-world testing before proceeding with this technology. The FCC also failed to study the impact on small business of transition to digital audio broadcasting. The FCC has taken no final action in this matter.

Issue: Auction of Spectrum at 39 GHz. In November 1999, the FCC released a supplemental notice of proposed rulemaking to auction spectrum licenses in the 39 GHz band on a geographic basis, by economic area (EA).

On December 8, 1999, Advocacy filed comments with the FCC objecting to the use of EAs as the basis for geographic licensing. EAs are large areas that encompass both urban and rural communities. Small businesses seeking to provide service at 39 GHz would be more likely to participate successfully in auctions for smaller areas that more closely resemble the areas these businesses would want to serve. Advocacy also pointed out that the FCC originally proposed the use of smaller areas but rejected that idea solely on the grounds that the issue was the subject of copyright litigation, which was delaying the implementation of the rulemaking.

The FCC's solution is to permit post-auction partitioning, but partitioning has not proven successful in the past. Licensees have been hesitant to give up portions of their spectrum license. Additionally, partitioning is inefficient, would tend to drive up the costs of licenses, forces companies to negotiate spectrum prices with potential competitors, and is no substitute for truly competitive auctions. The FCC has not taken further action in this proceeding, but has approved the use of EAs in auctions for licenses on other spectrum bands.

Issue: Auction of Spectrum at 24 GHz. In November 1999, the FCC proposed rules to govern the 24 GHz band, including auction rules. The FCC proposed offering the licenses on a geographic basis, according to EAs.

On December 9, 1999, Advocacy filed comments objecting to the use of EAs as the basis for geographic licensing. EAs are large areas that encompass both urban and rural communities. Small businesses seeking to provide service at 24 GHz would be more likely to successfully participate in auctions for smaller areas that more closely resemble the areas these businesses would want to serve. The FCC's solution is to permit post-auction partitioning, but as Advocacy has indicated in the context of the 39 GHz proceeding, partitioning is an unsatisfactory solution.

The FCC has adopted final rules incorporating its EA proposal. However, three of the five FCC commissioners issued separate statements indicating they may consider smaller geographic areas in future auctions to encourage small business participation. On July 25, 2000, Advocacy filed a petition for reconsideration of the FCC's decision.

Issue: Re-auction of Spectrum on the PCS C- and F-Blocks. In January 2000, two large carriers requested that the FCC lift its small business eligibility restrictions on certain C- and F-Block personal communications service (PCS) licenses. Most of the licenses had been issued to NextWave Personal Communications, Inc., under rules reserving the PCS C- and F-Blocks for small business. But the FCC cancelled the licenses for nonpayment and planned to reauction them.

Advocacy filed comments opposing the waiver requests. Small businesses could not hope to compete for these spectrum licenses against large businesses. The Telecommunications Act of 1996 requires the FCC to assure the dissemination of spectrum licenses among a variety of applicants, specifically including small businesses, and women- and minority-owned businesses.

In June 2000, the FCC published a notice of proposed rulemaking in which it proposed to open licenses in all markets to large applicants. Advocacy filed comments opposing this plan and urging the FCC not to change its rules, or at least to offer large businesses fewer licenses than the FCC proposed.

In August 2000, the FCC issued final rules in this proceeding, adopting its proposal to permit large businesses to bid on licenses previously reserved for small businesses. According to the new rules, the FCC will reconfigure each 30 MHz C-Block license into three 10 MHz licenses per geographic market. The FCC will divide the markets into two tiers, based on population. Tier 1 will consist of markets with greater than 2.5 million people, and the FCC will permit big business bidding on two out of three 10 MHz licenses in each Tier 1 market. Tier 2 will consist of all other markets, and the FCC will permit open bidding on one out of three 10 MHz C-Block licenses in Tier 2. The FCC also will open bidding for all 15 MHz C-Block licenses, all F-Block licenses, and all other unsold C-Block licenses.

Issues relating to the re-auction are currently before federal court. On October 5, 2000, Advocacy filed a petition for reconsideration of the FCC's decision, reiterating Advocacy's objections to eliminating the set-aside.

Issue: Amendment of Auction Anti-collusion Rules. In February 2000, the FCC proposed expanding its rules governing communications among spectrum auction participants. The new rules would prohibit communications regarding any applicant's bidding strategy and would require an applicant to report any violation of the anti-collusion rules. The FCC did not prepare a regulatory flexibility analysis in this case, but instead, certified that the proposed rule would not have a significant impact on a substantial number of small entities.

Advocacy filed comments on March 28, 2000, pointing out that the FCC's certification failed to include any factual basis for its judgment that the proposal would have no significant impact, as the RFA requires. In response to Advocacy's comments, on August 9, 2000, the FCC published a regulatory flexibility analysis. Advocacy again filed comments, on August 29, 2000, because the FCC's analysis did not describe the impact the rules would have on small business, nor did it propose alternatives to minimize this impact. The FCC has not taken further action in this proceeding, but has approved the use of EAs for other spectrum.

Issue: Auction of Spectrum in the 4.9 GHz Band. In February 2000, the FCC proposed rules to license spectrum in the 4.9 GHz band, which has been transferred from federal government use. The FCC proposed offering the licenses on a geographic basis, according to EAs.

On April 26, 2000, Advocacy filed comments objecting to the use of EAs as the basis for geographic licensing because small businesses seeking to provide service at 4.9 GHz would be more likely to participate successfully in auctions for smaller areas that more closely resemble the areas these businesses would want to serve. The FCC's solution is to permit post-auction partitioning, but as Advocacy has indicated in the context of the 24 and 39 GHz proceedings, partitioning has not worked in the past.

The FCC also failed to identify the significant impact EA licensing would have on small business, and failed to propose alternatives designed to lessen this impact. The FCC has not taken further action in this proceeding, but has approved the use of EAs for other spectrum.

Issue: Compatibility between Cable Systems and Consumer Electronics Equipment. The FCC proposed rules in April 2000 to establish labeling and copy protection standards regarding "cable-ready" digital broadcast equipment. Advocacy filed comments in this proceeding on May 24, 2000, indicating that the FCC's regulatory flexibility analysis failed to describe what burden the rules may impose on small businesses and failed to propose alternative measures. The FCC adopted final rules on September 14, 2000, and certified that the rules would not have a significant impact on a substantial number of small entities.

Issue: Modifications to Children's Television Programming Reports. In early April 2000, the FCC proposed continuing indefinitely broadcasters' children's television programming reporting requirements. Furthermore, the FCC proposed requiring broadcasters to file their reports on a quarterly basis instead of annually.

Advocacy submitted a letter to the FCC in late August 2000 stating that the IRFA prepared by the FCC regarding the extension of filing requirements of children's television programming reports complied with the RFA, as it adequately described projected compliance requirements and alternatives that would minimize significant economic impact. However, Advocacy strongly recommended an additional, supplemental IRFA

be completed if the FCC adopts the proposals made by the Center for Media Education in its comments, because that organization's proposals would greatly increase the compliance burdens of small broadcasters. The FCC released its final order while this report was being prepared, and the agency adopted Advocacy's suggestion to issue a separate rulemaking to consider the proposed additions to the reporting requirements.

Issue: Access Charge Reform and Universal Service. In July 2000, the FCC published an order that fundamentally changed how fees are assigned and collected between end-users, local exchange carriers, and inter-exchange carriers. The order concluded two major issue areas—access charge reform and universal service—that have been before the FCC since the passage of the 1996 Telecommunications Act. This order greatly increased the per-line fees on end users while reducing access charges that long-distance users pay to local carriers for originating and terminating long-distance phone calls. Certain long-distance carriers voluntarily committed to lowering long-distance charges for end users.

Advocacy filed a letter in September 2000 with the FCC, stating that there was scant evidence that the FCC considered the impact of this far-reaching order on small businesses or undertook even a modicum of effort to comply with the RFA. Specifically, Advocacy found that the FRFA was deficient because it failed to: (1) address the significant issues raised in public comment; (2) properly identify the small business entities impacted; and (3) consider significant alternatives proposed in the rulemaking. Advocacy recommended that the FCC stay any enforcement of its order until a revised FRFA is prepared and the order is amended based upon the conclusions of the new analysis. Advocacy recommended that the FCC host a public workshop or hearing to garner further input from small businesses during the course of re-evaluating the analysis.

Issue: Publication of Regulatory Flexibility Analyses in the *Federal Register*. In a series of regulatory actions throughout the first half of 2000, the FCC failed to include the regulatory flexibility analysis when it published its rules in the *Federal Register*. Advocacy filed a letter with the FCC in early September 2000 stating that the RFA requires regulatory flexibility analyses to be published in the *Federal Register*. Advocacy argued that the FCC's failure to do so frustrated one of the key elements of the RFA, dissemination of information for public comment, and denied small businesses a valuable tool in the regulatory process.

Federal Reserve System

The Federal Reserve is the central bank of the United States, founded by Congress in 1913, to provide the nation with a safer, more flexible, and more stable monetary and financial system. The Federal Reserve's duties fall into four general areas: (1) conducting the nation's monetary policy; (2) supervising and regulating banking institutions and protecting the credit rights of consumers; (3) maintaining the stability of the financial system; and (4) providing certain financial services to the U.S. government, the public, financial institutions, and foreign official institutions.

In March 2000, the Board of Governors of the Federal Reserve System (FRS) proposed a regulation to increase the percentage of equity capital that bank holding companies (BHCs) that qualify as financial holding companies (FHCs) must maintain in order to support merchant banking investments. The Gramm-Leach-Bliley Act, which became law in November 1999, expanded the types of merchant banking investments that BHCs and FHCs are authorized to make. The proposal sought to amend the FRS' consolidated capital guidelines for BHCs by increasing the charge against regulatory capital from the current limit of 8 percent to 50 percent. The FRS' reason for the increase is to control excessive risk associated with merchant banking and other investment activities.

Advocacy was concerned that this proposal could impact the level of BHC capital that will be available for investment in SBA-licensed small business investment companies (SBICs). Advocacy pointed out that commercial banks represent the largest source of SBIC private funding, and over the past 20 years the bank-owned SBICs have never had a year in which they lost money. Accordingly, Advocacy filed a comment letter with the FRS, stating that the proposal failed to comply with the RFA. Specifically, Advocacy argued that in applying a uniform increase in capital charges to all merchant banking activities, the proposal did not take into consideration the fact that SBICs have demonstrated extremely low risk to bank investors.

The public comment period on this rule closed in May, and at the end of fiscal year 2000, the FRS was still reviewing all of the comments received on the rule in order to consider whether to adopt this proposal.

Securities and Exchange Commission

In the aftermath of the stock market crash of October 1929, public confidence in the nation's securities market plummeted. The Congress found that the public's faith in the capital markets needed to be restored. Thus, in 1934, Congress established the U.S. Securities and Exchange Commission (SEC) to enforce newly passed securities laws, promote stability in the markets, and protect investors. Even today the SEC's primary mission is to protect investors and maintain the integrity of the securities markets.

Advocacy and the SEC have traditionally maintained a close working relationship in an effort to improve the regulatory environment for small businesses and small entities. While the SEC published a large number of rules in fiscal year 2000, most of Advocacy's involvement with the SEC concentrated on pre-proposal work and other efforts to promote regulatory policies that are more sensitive to small business concerns. For example, during fiscal year 2000, in performing its RFA activities, the SEC continued to consult with Advocacy and the SBA's Office of Size Standards on its proposed regulations that involved size standards issues. The SEC generally develops rules that define the small entities in industries that it regulates. However, whenever the agency faces situations where there is no established SBA or SEC definition of small business, the SEC has been diligent in consulting Advocacy and the Office of Size Standards to develop a size standard that works best for its regulatory purpose.

As in years past, Advocacy helped organize the 19th Annual Government-Business Forum on Small Business Capital Formation, which was held in San Antonio, Texas, in September 2000. This annual conference provides a unique opportunity for small business owners to meet with the staff of the SEC and articulate their views on how to eliminate unnecessary governmental impediments to raising capital and seeking credit. By spending two full days together, small business owners and federal public policymakers are able to develop concrete recommendations on improving the existing securities, tax, and banking regulations that affect small businesses.

Federal Procurement

Federal acquisition reform has been a major issue for Congress and regulatory agencies since 1994. During the 1994-1997 period, the administration and the United States Congress reached a policy consensus on the need for acquisition reform and several

reform measures were legislatively implemented. Some of the changes required a total revamping of the federal acquisition process. The major thrust of the reform movement was to streamline the process for procuring goods and services. The intent was to make the federal marketplace look, be, and act like the commercial world. If this transformation were successful, then the federal government would be assured that its nearly $200 billion procurement budget would achieve greater spending power.

In 1994, Congress enacted the first of several major reform laws—the Federal Acquisition Streamlining Act of 1994. The Federal Acquisition Reform Act of 1996 was the next major legislative change. These two laws have become the centerpieces of governmental procurement reform, and by 1998, the impacts of the laws were beginning to affect the procurement marketplace. In 1999, several post-acquisition reforms emerged that had the potential to become burdensome to the small business community. The most visible was the apparent decline in the prime contract dollars awarded to small business. This was not the intent of the procurement reform efforts.

Fiscal year 2000 began with some agencies proposing regulatory procurement changes to lessen the negative impact of acquisition reform on small businesses. Public Law 93-400 created the Office of Federal Procurement Policy (OFPP) and the Federal Acquisition Regulation (FAR) Council. The FAR Council is charged with the responsibility of assisting in the direction and coordination of federal government-wide procurement policy and regulatory activities. The membership of the FAR Council consists of the Administrator for Federal Procurement Policy, the Secretary of Defense, the Administrator of the National Aeronautics and Space Administration (NASA) and the Administrator of the General Services Administration (GSA).

The most significant change in fiscal year 2000 involved the FAR Council and SBA promulgating final “contract bundling” regulations. Procurement reform made it easier for procuring activities to combine several small business contracts into one multi-million-dollar bundled contract. Once bundled, these contracts usually are too large for small businesses to win in full and open competition. These regulations are designed to protect the small business community by giving the procuring activity clear guidelines and procedures to follow when small business contracts are taken for bundling.

Another milestone that emerged in fiscal year 2000 was the increased level of awareness by the FAR Council and other agencies of the statutory review power of

Advocacy on their procurement regulatory process. The OFPP, the FAR Council, and several other agencies began to request Advocacy's advice prior to proposing procurement regulatory changes. For example, DOC requested input on its now-published proposed regulation on rights to inventions made by nonprofit organizations and small business firms under government grants, contracts, and cooperative agreements. The DOT requested that Advocacy review its pre-proposed regulation on bundling. The Department of Veterans Affairs (VA) has also worked very closely with Advocacy to prepare an IRFA for a proposal to simplify its acquisition regulations for commercial health care resources.

Environmental Protection Agency

Issue: Regulation on Collection of Race and Ethnic Data from Successful Offerors. On June 23, 2000, the EPA published a proposed rule to amend the EPA acquisition regulation. The rule would add a new clause designed to provide the EPA with information regarding its contract awardees. This new clause required the successful offeror of an EPA contract to voluntarily identify the specific racial/ethnic category that best represents the ownership of the business. The agency certified that this proposed rule would not have a significant impact on a substantial number of small entities.

Advocacy provided comments on the proposed rule. Advocacy argued that the certification was flawed, as it lacked documentation to support the agency's conclusion that the rule would not have a significant impact on a substantial number of small entities. More specifically, Advocacy said that the proposed rule would establish a definition for business ownership of racial/ethnic persons that would appear to be different from the current definition in FAR (52.219) and Title 13 of the *Code of Federal Regulations*, part 124.102. Further, even if one were to agree that the definitions are different, compliance with the proposed rule is voluntary and thus EPA does not provide a compelling justification for its deviation from the FAR and Title 13 of the *Code of Federal Regulations*. Advocacy's comment letter requested EPA to conduct an IRFA before proceeding with this regulation.

Federal Acquisition Regulation Council

Issue: Regulation on Enhancement of Small Business Participation on Federal Supply Schedules. On November 22, 1999, Advocacy provided comments to FAR case 98-609, on the Federal Acquisition Regulation, Federal Supply Schedules (FSS) Small Business Opportunities. The proposed regulations would require the enhancement of small business participation on federal supply schedule programs by encouraging ordering offices to consider small business when conducting evaluations before placing an order. Acquisition reform has created a tremendous demand for the use of

FSS. While small businesses were being awarded the opportunity to participate on FSS, many small businesses were not selected by the contracting agency. In the contracting community, FSS are considered a license to market. The ordering office has the authority to select any vendor from the schedule. This FAR case provides additional guidance to this selection process.

Advocacy expressed concern that the FAR Council provided an insufficient factual basis in its IRFA for the small business community to evaluate the potential impact of the proposed regulation. Notwithstanding Advocacy's position, the FAR Council published the final rule. The agency's FRFA did, however, recognize some of the problems encountered by small businesses in competing against large businesses for FSS work.

Issue: Regulation on Contractor Responsibility. On July 9, 1999, FAR case 99-010, Contractor Responsibility, Labor Relations Cost, and Costs Relating to Legal and other Proceedings, was published in the *Federal Register*. By law, federal agencies can award contracts only to "responsible sources." The proposed rule would have provided the contracting officer with authority to reject an apparent successful bid if the contractor had been the subject of a specified conviction, judgment, or adverse decision in the previous three years. The hierarchy of offenses included the areas of tax, labor, antitrust, environmental, and consumer protection laws. On November 8, 1999, Advocacy provided formal comments on this proposed rule. Advocacy noted that the FAR Council did not provide an IRFA addressing the impact of this proposed rule on small entities. Instead, the FAR Council attempted to certify the proposed rule. Advocacy expressed concern with the FAR Council's lack of a factual basis for its RFA certification of no significant impact.

The FAR Council received more than 1,500 comment letters on this proposed rule. As a result, a revised proposed regulation on contractor responsibility was published on June 30, 2000. This became FAR case 1999-010. The FAR Council agreed with Advocacy's position that a regulation of this sweeping magnitude should include an IRFA. An IRFA was in fact published with the revised proposed regulation.

On August 29, 2000, Advocacy submitted a formal comment on the revised proposed rule. Advocacy argued that the IRFA raised additional questions about the level of impact on a substantial number of small entities. For example, the IRFA did not provide a factual basis on the number of small businesses formally charged with infractions

covered by the proposed regulation. The IRFA also failed to provide a factual basis for the estimation of the number of small businesses that would be suspended for any period of time from doing business with the federal government. Advocacy's comment letter asked for a more detailed IRFA to be published before any final regulation was issued.

Entities Not Covered by the RFA

Internet Corporation for Assigned Names and Numbers

The Internet Corporation for Assigned Names and Numbers (ICANN) is a nonprofit private sector entity that was designated by the DOC to oversee technical management of the Internet. Because ICANN is not a federal government agency, it is not covered by the RFA. However, ICANN has been given a great deal of authority over the Internet and the policies that it sets will have immense impact on companies that use the Internet.

Issue: Introduction of New Top-Level Internet Domains. In early December 1999, ICANN's Working Group C released an interim report on possible methods of introducing new top-level domain (TLD) names to the Internet. In early January 2000, Advocacy submitted comments to Working Group C supporting the introduction of an unlimited number of new TLDs at a gradual pace following a limited introduction and evaluation period. Advocacy also recommended that ICANN define the technical criteria for the evaluation beforehand and commit to introducing additional TLD names if the criteria were met. Advocacy stated that limited safeguards for trademark holders are appropriate as long as the safeguards do not expand trademark rights and are balanced with the interests of registries and domain name registrants.

In early April, Working Group C submitted its report to the Names Council, which is the administrative body of the Domain Name Supporting Organization. In mid-April, the Names Council gave its recommendation to the ICANN board that it establish a policy for the introduction of new TLDs in a measured and responsible manner. The Names Council recommended a test-bed period where a limited number of new TLDs would be introduced and evaluated before more are introduced.

Advocacy submitted a letter to ICANN in July 2000 summarizing its earlier position and supporting the introduction of new TLDs. At its July 2000, meeting in Yokohama, Japan, ICANN approved a resolution to add new TLDs to the Internet and initiated a process to accept applications to run them.

Issue: Protection of Famous Marks on the Internet. ICANN created a committee and tasked it with developing ideas on the protection of famous marks on the Internet. Designated as Working Group B, this committee was composed of interested volunteers and was open to the public. Its decisions were made by consensus of the group.

In March 2000, Working Group B released a report on the relationship of the protection of trademarks and registering TLDs. Advocacy submitted comments on the report in early April 2000, noting serious concerns that the proposed protections for famous marks would preclude small businesses from using common, everyday words, as well as common family names as domain names on the Internet. Therefore, Advocacy argued that Working Group B's conclusion that famous marks could best be protected through the use of a "sunrise proposal" would have a detrimental impact on small business and should not be adopted.

The sunrise proposal would establish a pre-registration period for trademark holders every time a new TLD is introduced. During the sunrise period, trademark holders could register names corresponding to their trademark and 20 variations of it. Instead, Advocacy recommended that Working Group B adopt one of three alternatives: (1) introduce a large number of new TLDs; (2) create chartered new TLDs for use by trademark holders; or (3) adopt a variation of the modified sunrise proposal. Alternative three would permit a holder of a registered trademark to register the name identical to its trademark during a sunrise period. However, this would apply only to chartered TLDs where the charter corresponds to that trademark's international class of industry and service.

In April 2000, over Advocacy's objections, the Names Council of the Domain Names Supporting Organization supported and published the formal report of Working Group B and requested comments. Advocacy sent letters to small business trade associations informing them of the sunrise proposal and encouraging them to comment on the issue.

At its Yokohama, Japan, meeting in July 2000, ICANN chose not to adopt the sunrise proposal. Instead, ICANN requested that each applicant include a section in the proposal on how to protect intellectual property. Several of the new proposed TLDs included a sunrise proposal, while others did not.

United States Postal Service

The United States Postal Service (USPS) is an independent establishment of the executive branch. It provides mail processing and delivery services to individuals and busi-

nesses in the United States. USPS is also responsible for protecting the mails from loss or theft, and apprehending those who violate postal laws.

Issue: Regulation on Commercial Mail Receiving Agencies. The USPS is an agency whose rules are not subject to the notice and comment provisions of the APA. As such, it is not subject to the RFA.[12] Nevertheless, Advocacy relied on the principles underlying the RFA to address concerns raised by small entities when USPS promulgated a rule concerning commercial mail receiving agencies (CMRA).

On March 25, 1999, USPS published a final rule in the *Federal Register* on delivery of mail to CMRAs. At the time that the rule was finalized, USPS asserted that "the sole postal purpose of the rule is to increase the safety and security of the mail." Among other things, the rule required CMRA users to use the terms, "private mail box" (PMB), in their mailing addresses, provide two forms of identification when renting a mailbox, and file a PS Form 1583 with USPS disclosing the actual location of the user. The form would be publicly available. If a CMRA user did not comply with the rule, USPS stated that its mail would not be delivered.

Although USPS received over 8,000 comments in opposition to the proposal and only 10 in favor, USPS nevertheless finalized the rule. In promulgating the rule, USPS asserted that the rule was necessary to combat mail fraud. However, the agency did not provide any statistics or studies to substantiate its claim that fraud occurred at any greater rate at CMRAs than at USPS post office boxes.

Advocacy became involved with this issue when small businesses notified Advocacy about the impact of the rule. Advocacy then held roundtable discussions and conference calls with affected small entities. Advocacy also sent letters to the Postmaster and attended meetings to present the views of small businesses. In its correspondence to USPS, Advocacy pointed out that the rulemaking was not only discriminatory and arbitrary,[13] it was extremely costly to small businesses. The USPS allowed users one year to add "PMB" to the address before stopping mail delivery. However, it did not take into account either the loss that small businesses would suffer when customers, relying on address information contained in old materials, tried to contact the business, or the stigma that small businesses could experience due to the use of the term PMB in

12. Section 601 of the RFA uses the same definition of "agency" as found in 5 U.S.C. § 551(1). See 5 U.S.C. § 601. Pursuant to 39 U.S.C. § 410, the USPS is exempt from complying with § 551 of Title 5.

13. Advocacy made this argument because it applied only to CMRA facilities and not to other bulk mail types of receiving facilities such as hotels, colleges, corporate suites etc. Moreover, there was no information to indicate that fraud was occurring at any greater rate at CMRAs than through the regular mail, USPS postal boxes, or other means of delivery.

a mailing address. Furthermore, small businesses feared that there were safety concerns regarding the release of the actual location of a CMRA user. USPS has since announced that it will release information about the actual address of the CMRA user only upon receipt of a subpoena or a court order, thus addressing one of the security concerns raised by many users.

On March 13, 2000, USPS published a proposed rule on delivery of mail to commercial mail receiving agencies. The proposal revised the requirement that private mailbox users use the term PMB in their addresses. The proposed rule amended the CMRA rule that was finalized in March 1999, by allowing CMRA users to use the "pound" (#) sign instead as an alternative to the PMB designator. The proposal also allowed CMRA users to use three-line addresses. In the proposal, USPS stated that although small business groups have indicated that the PMB requirement may have a negative impact on the businesses of CMRA mailbox holders, USPS was not convinced that negative perceptions would occur. Nevertheless, USPS asserted that it was proposing the revision in an attempt to balance the goal of protecting the public with the concerns of the small business community.

On April 12, 2000, Advocacy filed comments on the proposal. Advocacy again argued that USPS did not have a rational basis for implementing the rule, and that the rule discriminated against CMRA users. Advocacy also raised a concern about USPS requiring all CMRAs to adopt the "#" sign requirement, which was a contractual obligation for Mailboxes, Etc., customers but not necessarily for customers of independently owned CMRAs. Advocacy argued that a government agency imposing the requirements of a large corporation on smaller competitors gave the appearance of impropriety and interfered with competition.

In August 2000, USPS finalized the # sign alternative. In doing so, it also extended the compliance deadline from August 26, 2000, to August 26, 2001.

World Intellectual Property Organization

The World Intellectual Property Organization (WIPO) is an international organization that promotes the use and protection of intellectual property. WIPO is one of the 16 specialized agencies of the United Nations system of organizations. It has 175 nations as member states. WIPO administers 21 international treaties dealing with different aspects of intellectual property protection. As an international organization, WIPO is not covered by the RFA.

Issue: Second Internet Domain Name Process. In early July 2000, the WIPO released a report that identified a series of issues concerning intellectual property rights on the Internet. WIPO sought public comment on the validity of the intellectual property rights issues identified in the report and whether additional issues should be addressed. Advocacy submitted a letter to WIPO in mid-September 2000, recommending that it request additional comments on: (1) why current legal protections are insufficient to protect intellectual property rights; (2) why additional protection is needed in the areas identified by the WIPO and not in other areas; (3) how changes in policy that alter the relationship between trademarks and domain names will affect the nonprotected class; (4) how different proposals will affect the domain name system; and (5) how each of the issues in WIPO's report interacted with third-party law, actions, and policies. Advocacy also recommended that the WIPO clarify the issues that were presented in the report. To date Advocacy is awaiting action by the WIPO on these issues.

Appendix C: Regulatory Cost Savings for Fiscal Year 2000

The following details rulemaking activities that the Office of Advocacy was involved in during fiscal year 2000 that resulted in cost savings to small businesses. The combination of yearly savings and one-time savings during this period totals almost $3.6 billion.

Agency	Subject Description	Cost Savings
AMS	*National Organic Program.* This rule issued by the Agricultural Marketing Service set national standards for producing and selling organic products.	Cost savings estimate not available.
BLM	*3809 Hardrock Mining Reclamation Bond Rule.* The Bureau of Land Management requires hardrock miners to provide reclamation bonds for mining on federal lands. This rule was the subject of the *Northwest Mining v. Babbitt* case in which, in May 1998, the court remanded the rule to BLM for its failure to comply with the RFA, as requested by Advocacy in its *amicus curiae* brief. Although the agency has since re-proposed the rule, it has not yet been finalized. Thus, until the rule is final, small businesses do not need to comply with the bond requirement.	**$150 million in annual savings** Source: BLM draft cost-benefit analysis for the Draft Final 3809 Hardrock Mining Rule. This cost estimate includes compliance costs and the value of foregone mineral production.
EPA	*Concentrated Animal Feeding Operations (CAFO) Clean Water Act Regulations.* This Environmental Protection Agency rule expands and revises Clean Water Act regulations that define what is a CAFO, and establish permit requirements and technology-based water pollution standards for CAFO.	**$9 million in annual savings**[1] Source: The Office of Advocacy, based on EPA's economic analysis in the rulemaking record.
EPA	*Control of Hazardous Air Pollutants from Reinforced Plastics Composites Industry.* This rule sets technology-based standards for the reinforced plastics composites industry.	**$68 million in annual savings** Source: The Office of Advocacy, based on EPA's economic analysis in the rulemaking record.
EPA	*Control of Hazardous Air Pollutants from Secondary Aluminum Industry.* This rule sets technology-based standards for the secondary aluminum industry.	**$20 million in annual savings**[2] Source: The American Foundrymen's Society, Inc.
EPA	*Tier 2 Gasoline Sulfur Standards Air Pollution Rule.* This rule sets engine and vehicle standards for medium and light duty vehicles. It also sets standards for sulfur in gasoline.	**$91 million in annual savings** Source: The Office of Advocacy, based on EPA's economic analysis in the rulemaking record.
EPA	*Transportation Equipment Cleaning Industry.*This rule set controls for water pollution discharges from transportation industry vehicles such as trains, buses, trucks, and ships.	**$5 million in annual savings** Source: The Office of Advocacy, based on EPA's economic analysis in the rulemaking record.
EPA	*Underground Injection Well—Class V Safe Drinking Water Rule.*This rule regulates the discharge of chemical wastes into drinking water.	**$10 million in annual savings** Source: The Office of Advocacy, based on EPA's economic analysis in the rulemaking record.

1. The cost savings is the difference between the option originally preferred by the EPA and the one finally selected in the rule. The EPA had originally developed two sets of cost estimates, leading to two estimates of cost savings. As a result, the Office of Advocacy estimates that the savings for this rule range from $2 million to $15 million per year. The arithmetic average of the two figures, rounded to the nearest million, equals $9 million.
2. With a 4-year deferral of the compliance date for the final standard, small refiners realize a net cost savings for the final rule relative to the proposed rule. Using EPA's 15-year project life for the pollution control equipment and OMB's recommended 7 percent discount rate, the one-time and corresponding equivalent annual net cost savings were calculated. The one-time savings total approximately $800 million. The equivalent annual savings are $91 million.

Agency	Subject Description	Cost Savings
FDA	*Dietary Supplement Labels Containing Structure/Function Claims*. This Food and Drug Administration rule prohibits the manufacturing of dietary supplements that make claims regarding the effects of the drug on the body.	Cost savings estimate not available.
FDA	*Drug Pedigree Requirements.* This rule requires drug wholesalers to maintain records of each prior handler of the drug.	Cost savings estimate not available.
FDA	*Sterility Requirements for Aqueous-Based Drug Products.* This rule requires manufacturers of aqueous-based inhalation products to use a sterile process in the manufacture.	**$10.1 million in one-time savings** Source: FDA's statement in the final rule, 65 *Fed. Reg.* 34,082, 34,087 (2000).
FS	*Roadless Conservation Rule*. This Forest Service rule prohibits the construction and reconstruction of roads in inventoried roadless areas found in national forest lands. Initially, FS alleged that the rule would not have a significant economic impact on small entities, including small timber and mining operations and communities dependent on revenues from timber sales. The Office of Advocacy disagreed and urged the FS to solicit information on the exact impact. Small communities responded rather dramatically. To offset this loss, Congress enacted the Secure Rural Schools and Community Self-Determination Act, which continues distributions to the states through 2006. The revenues are estimated to be approximately $135,006,000 per year, based on 1997 numbers.	Cost savings estimate not available.
HCFA	*Home Health Care Prospective Payment System.* With this rule, the Health Care Financing Administration established a new Medicare reimbursement system for home health care agencies.	Cost savings estimate not available. Note: At the time of the printing of this report, additional "giveback" legislation (to give health providers more Medicare dollars) was being considered by Congress.
HCFA	*Hospital Outpatient Prospective Payment System.* This rule established a new Medicare reimbursement system for hospital outpatient services.	Cost savings estimate not available. Note: At the time of the printing of this report, additional "giveback" legislation (to give health providers more Medicare dollars) was being considered by Congress.
HHS	*Health Information Privacy.* This Department of Health and Human Services rule established privacy standards for transferring electronic medical records.	Cost savings estimate not available.
OSHA	*Safety and Health Program Rule.* With this rule, the Occupational Safety and Health Administration requires every business owner to have a safety and health program to prevent injuries and illnesses in the workplace. However, OSHA has indefinitely delayed the final implementation of the rule. The Office of Advocacy believes that the SBREFA panel report played a significant role in the agency's decision to reconsider promulgating the rule.	**$3 billion in one-time savings** Source: OSHA's estimate of the entire cost of the rule at the time of proposal.
PWBA	*ERISA Benefit Claims Rule*. This Pension and Welfare Benefits Administration rule sought to require every employee welfare plan under ERISA, such as a pension or health plan, to establish new procedures to advise its beneficiaries about their ability to appeal a denial of benefits. PWBA estimated that it would cost approximately $100 million for small businesses to amend their employee plans. Advocacy argued that the compliance cost would be at least $220 million, which is a significant burden to small pension plans. Additionally, Advocacy indicated that the record of small pension denial claims did not justify this regulatory action. PWBA agreed, and excluded small pension plans in the final version of the rule, thereby avoiding the need for approximately 635,000 small businesses to amend their plans.	**$220 million in one-time savings** Source: The Office of Advocacy, based on PWBA's estimates contained in other regulations and from industry estimates.

Agency	Subject Description	Cost Savings
USPS	*Commercial Mail Receiving Agencies/Private Mailbox Rule.* With this rule, the United States Postal Service requires users of commercial mail receiving agencies to use the term, "PMB," or the pound (#) sign in their mailing addresses. The implementation of the rule was delayed two and one-half years to allow sufficient time for small businesses to phase out the use of old stationery and other business materials prior to obtaining materials that complied with the rule.	Cost savings estimate not available.

Subtotals:	**$353 million** in annual savings, and **$3,230.1 million** in one-time savings
Grand Total Cost Savings:	**$3,583,100,000 (almost $3.6 billion)**

Appendix D: The Regulatory Flexibility Act: Changing the Culture of Federal Agencies

Synopsis

The Regulatory Flexibility Act of 1980 is an important statute that has changed the way federal regulatory agencies relate to small businesses in crafting regulations. The law seeks to level the regulatory playing field for small businesses and preserve competition in the marketplace by forcing agencies to undertake a thorough analysis of the economic impact of their proposed regulations and to consider alternatives that will achieve the same public policy goals, but with more equitable impact on small entities.

While it took nearly 20 years of persistent effort on the part of Congress, the Small Business Administration's (SBA) Office of Advocacy, and small businesses, as well as litigation and amendments to the law, the Regulatory Flexibility Act has changed how regulatory agencies evaluate regulations.

Background

Before the Regulatory Flexibility Act (RFA) was enacted in 1980, federal agencies generally did not recognize the impact their rules would have on small businesses, nor did they readily understand the fact that small businesses would suffer disproportionately—compared with large businesses—from those regulations.[1] More often than not, the agencies failed to recognize or understand the important role small businesses play in the economy.

The 1980 White House Conference on Small Business

In 1980, when hundreds of small business owners from across the country convened in Washington, D.C., to participate in the first White House Conference on Small Business, their message to President Jimmy Carter and the Congress was loud and clear. They demanded relief from burdensome federal government mandates and argued for more flexible regulations.

Small businesses argued that when a federal agency issues a regulation, the burden of that law often falls hardest on them. This occurs, not through any intentional desire by

Note: This appendix was prepared in 1999 as a chapter for *The State of Small Business: A Report of the President.*

1.The Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (codified at 5 U.S.C. § 601 et seq.), became law on September 19, 1980.

the agency to overregulate them, but rather because "one-size-fits-all" regulations impose disproportionate costs on small entities. For example, the direct costs involved in complying with a regulation are approximately the same for a large company as for a small company. But since a large company is able to spread the compliance cost—such as additional staff time and resources and fees for professional services—over larger output, it has the ability to maintain a competitive advantage over a small company.

Additionally, because large businesses can afford to hire more people—both within their companies and as professional representatives in Washington—to monitor proposed agency regulations and thereby have easier, more direct input in the regulatory process, small businesses are inherently at a disadvantage in their ability to influence the outcome of regulatory decisions.

Congressional Response to Small Business Concerns

Recognizing the disparity in the level of input during the rulemaking process, as well as the disparate impact on small businesses upon implementation of regulations, the U.S. Congress responded to small business concerns by enacting the RFA. Congress agreed with small businesses and made specific findings in the preamble to the RFA that "laws and regulations designed for application to large scale entities have been applied uniformly to small [entities, ...] even though the problems that gave rise to the government action may not have been caused by those small entities."[2] As a result, Congress found that these regulations have "imposed unnecessary and disproportionately burdensome demands" upon small businesses with limited resources, which, in turn, have "adversely affected competition."[3]

To counteract the traditional, one-size-fits-all regulatory mindset of the regulators, the RFA establishes "as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses."[4] To achieve this principle, Congress mandated that "agencies are required to solicit and consider flexible regulatory proposals and to explain their rationale for their actions to assure that such proposals are given serious consideration."[5]

Requirements of the Regulatory Flexibility Act

Specifically, the RFA requires agencies to review their regulatory proposals and determine if any new rule is likely to have a "significant economic impact on a substantial number of small entities."[6] If such impact is likely to occur, the RFA then requires the agencies to

2. *Findings and Purposes,* Pub. L. No. 96-354.
3. *Id.*
4. *Id.*
5. *Id.*
6. 5 *U.S.C.* §§ 602(a)(1), 605(b).

prepare and make available for public comment an "initial regulatory flexibility analysis," describing in detail the potential economic impact of the proposed rule on small entities.[7]

As an essential part of this analysis, agencies are required to identify alternatives to the proposed rule that accomplish the stated objectives of applicable statutes but minimize any significant economic impact of the proposed rule on small entities.[8] A similarly detailed regulatory flexibility analysis is also required for final rules, which also must be made available to the public.[9]

By mandating this economic analysis, the RFA seeks to ensure that agencies spend the necessary time and resources to identify and understand the potential impact of their regulations on small entities before it is too late to pursue alternative measures. To accomplish this, agencies must solicit meaningful input from the small business community early in the rulemaking process.

The RFA was also based on the rationale that when an agency undertakes a careful analysis of its proposed regulations—with sufficient small business input—the agency can, and will, identify the disproportionate economic impact on small businesses. Once an agency realizes that a rule will have such an impact on small businesses, it is expected to seek alternative measures to reduce or eliminate the disproportionate burden without compromising public policy objectives.

The RFA also contains measures to ensure agency compliance with the law, such as authorizing the chief counsel for advocacy to appear as *amicus curiae* ("friend of the court") when an entity appeals an agency's final action.[10]

Federal Agencies' Response to the Regulatory Flexibility Act

In monitoring agencies' compliance with the law over the years as RFA mandates, the Office of Advocacy (Advocacy) found that federal agencies, more often than not, failed to conduct the analyses mandated by the RFA. Some agencies ignored the RFA altogether, while others asserted that the RFA did not apply to them. Other agencies recognized the RFA's applicability to their regulatory process yet failed to comply with the letter and spirit of the law. For example, the RFA authorizes an agency to forego the preparation and publication of initial and final regulatory flexibility analyses for public comment "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."[11] Several congressional hearings documented that many agencies simply fell into a habit

7. *Id.* § 603.
8. See *id.* § 603(c).
9. See *id.* § 604.
10. *Id.* § 612(b).
11. *Id.* § 605(b).

of certifying that their rules would have no impact without demonstrating the basis for such a conclusion. It was clear that using "boilerplate" language in rule after rule did not comport with the RFA's mandate.

Equally troubling was the finding that agencies often did not understand or accept the possibility that less burdensome regulatory alternatives may, in fact, be equally effective in achieving public policy objectives. This mistaken assumption meant that many agencies failed—or even refused—to consider valid alternatives for their proposals even when such options were brought to their attention by small businesses during the rulemaking process. The agencies' failure to weigh alternatives properly not only defeats the core purpose of the RFA; it effectively excludes small businesses from a meaningful opportunity to influence the regulatory development process as the Congress intended.

Finally, because the RFA as originally enacted in 1980 did not provide for judicial review of compliance with the RFA, the small business community was left with no remedy to enforce compliance. Similarly, while the RFA authorized the SBA's chief counsel for advocacy to file *amicus* briefs in regulatory appeals, the issue of agency noncompliance could not be raised because the courts did not have jurisdiction over the question.

The 1995 White House Conference on Small Business and SBREFA

Small businesses had an opportunity to point out these shortcomings in the RFA at the 1995 White House Conference on Small Business. They urged the administration and the Congress to pass amendments that would add “teeth” to the law.

In response, in 1996, Congress enacted the Small Business Regulatory Enforcement Fairness Act (SBREFA), which amended the RFA in several critical respects.[12] With agencies' pattern and practice of noncompliance in mind, Congress designed the SBREFA amendments to the RFA to ensure meaningful small business input during the earliest stages of the regulatory development process.[13] The amendments also required agencies to provide more detailed and substantive analyses of regulatory economic impacts. SBREFA reaffirmed the authority of the chief counsel for advocacy to file *amicus curiae* briefs in regulatory appeals brought by small entities.

Most important, the SBREFA amendments added two new provisions to the RFA:

12. The Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104-121, 110 Stat. 857 (codified at 5 U.S.C. § 601 et seq.), was signed by President Clinton on March 29, 1996.
13. See *Findings*, Pub. L. No. 104-121 (“Congress finds that [RFA requirements] have too often been ignored by government agencies, resulting in greater regulatory burdens on small entities than necessitated by statute.”)

- Small Business Advocacy Review Panel Process: SBREFA mandates that structured review panels be convened to ensure small business participation in the development of rules by the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA) when such rules are anticipated to have a significant impact on a substantial number of small entities.

- Judicial Review of Agency Compliance: SBREFA authorizes aggrieved small businesses appealing from agency final actions to seek judicial review of agency failure to comply with the RFA.

The RFA Today: Federal Agencies' Response to the SBREFA Amendments

In the years since SBREFA amended the RFA, the regulatory environment for small businesses has begun to change for the better. As highlighted in the chief counsel for advocacy's annual reports on RFA, over the past few years, small businesses have played active roles in bringing about some fundamental changes in the way federal agencies view the RFA and their responsibilities under the law.[14]

Numerous agencies have implemented changes to their regulatory processes, including noticeably enhanced outreach efforts to small businesses and internal training and resources committed to ensure adequate regulatory flexibility analyses. Other agencies are learning to comply with the RFA the hard way through litigation and are carefully monitoring the latest court cases resulting from the judicial review provisions of the RFA.

Most significantly, agencies and the Congress are paying special attention to the changes brought about by the addition of the small business advocacy review panel process. As a procedure for gathering public comments, this SBREFA amendment to the RFA mandates that small business representatives be consulted by policymakers of EPA and OSHA, two agencies that have major impact on a wide range of industries dominated by small businesses. The panel process allows small businesses to find their seat at the regulatory table, and this new process is making a difference.

Agencies are Conducting More Effective Small Business Outreach

Thanks to the RFA and SBREFA, agency outreach to small businesses has grown significantly. Almost every federal agency today incorporates a wide variety of mechanisms to reach out to the communities affected by its regulations. For example, agencies routinely participate at industry conferences; host regional roundtable meetings;

14. See, e.g., U.S. Small Business Administration, Office of Advocacy, *Annual Report of the Chief Counsel for Advocacy on Implementation of the Regulatory Flexibility Act*, Reports for Calendar Years 1996, 1997, 1998, 1999.

answer inquiries from small businesses via mail, fax, and electronic mail; and use the Internet and toll-free telephone numbers to encourage easy access to information for small businesses.

The Department of Housing and Urban Development (HUD)'s outreach efforts are especially noteworthy. Like many other agencies, HUD uses its Office of Small and Disadvantaged Business Utilization (OSDBU) to monitor RFA compliance. However, HUD has worked hard to identify the most appropriate small-entity representatives to receive its information. HUD's OSDBU has written to more than 700 trade associations and minority- and woman-owned business chambers of commerce advising them of the small business rights under the RFA as amended by SBREFA. From the very beginning of the process, HUD has also taken aggressive measures to include small businesses in "negotiated rulemakings" on regulations dealing with manufactured housing, real estate settlement procedures, Indian housing, lead-based paint, and public housing.

While outreach is certainly a necessary first step, the test of the process' effectiveness is whether the agency considers small business input in its decisions. Few agencies—although an increasing number—can cite instances in which they changed proposed regulations as a result of discussion with small business entities.

One independent agency, the Securities and Exchange Commission (SEC), provides a compelling success story. The SEC has had a long history of engaging in deregulatory efforts to assist small businesses in their capital-raising transactions. In order to determine where regulatory assistance might be most useful, the SEC initiated a series of "town hall" meetings across the nation to learn from the entrepreneurs they regulate. Since 1982, the SEC has also hosted an annual forum on small business capital formation where small business owners and their advocates spend two days with government officials to discuss regulatory changes that could address their concerns. Members of Congress and other interested parties receive written summaries of the discussions and the recommendations that resulted and many recommendations have been implemented.

The SEC also actively educates its staff about small business issues. The SEC's internal training activities for its compliance and enforcement personnel incorporate information on RFA and SBREFA. SEC staff, including economists, who engage in rulemaking activities receive specialized training in all aspects of legally required administrative procedures.

This intensive outreach effort and RFA training paid off on at least one occasion when a proposed SEC rule was revised because of a thorough regulatory flexibility analysis. Rule 504 of the SEC regulations permitted small companies to raise up to $1 million in "seed capital" in a 12-month period with minimal compliance requirements.[15]

Because of the simplicity of the rule's requirements, however, unscrupulous securities promoters abused the rule. In addressing the abuse, the SEC proposed a change that would restrict securities issued pursuant to Rule 504 from subsequent transferability. During the rulemaking process and its accompanying regulatory flexibility analysis, the SEC realized the proposed revision would adversely affect companies—especially the smallest ones—by making it more difficult to raise capital. The small businesses that commented on the rule explained that amending the liquidity option would increase the cost of raising capital, and in some cases even eliminate the market.

Upon further analysis and careful consideration of alternatives, the SEC revised the proposal to preserve the liquidity option for small companies while still addressing the potential for abuse. By complying with the RFA, the SEC achieved its policy objective of protecting investors and limiting the potential for abuse without harming small business interests.

Agencies are Working to Comply with the RFA

In addition to outreach, more and more agencies are asking for guidance in complying with the RFA and redirecting agency resources to the actual task of complying. Compliance with the RFA early in the regulatory process not only benefits small businesses; it saves time, produces better regulatory proposals, and avoids litigation for the agencies.

The Department of Agriculture (USDA) is a typical example. For a number of years, the USDA's Agricultural Marketing Service (AMS) refused to acknowledge that its regulations were subject to the requirements of the RFA. Shortly after passage of SBREFA, however, AMS agreed to train its employees in compliance with the RFA, with the result that the Organic Program Office sought input on a new regulation to impose federal standards for labeling and producing organic products. This organic regulation marked the first time since the passage of the RFA in 1980 that AMS sought assistance and input on RFA compliance prior to publishing a proposal. Subsequently, AMS has tried to include initial or final regulatory flexibility analyses in nearly all of its proposed and final regulations.

The Department of Health and Human Services, Health Care Financing Administration

15. 17 *C.F.R.* § 230.504

(HCFA) provides another example. Since SBREFA amended the RFA, HCFA has instituted new procedures to seek input on controversial or burdensome regulations during the earliest stages of rulemaking, and the administrators of HCFA and SBA have met to discuss RFA compliance and related issues. In addition, SBA conducted two day-long RFA/SBREFA training sessions for HCFA employees. HCFA's commitment to comply with the RFA has been apparent on a number of occasions when HCFA submitted draft rules for early small business impact review.

One of the best examples of the benefits to be derived from efforts to ensure compliance with the RFA comes from the Department of Transportation (DOT). To implement provisions of the Americans with Disabilities Act, DOT proposed a regulation in March 1998 that would have required all newly purchased over-the-road buses to be accessible to passengers with disabilities. The rule also would have required all motor carriers, tour bus operators, and other transportation companies to provide accessible over-the-road bus service. Advocacy advised DOT that its proposed rule would have a serious impact on the small bus industry and would cause these small businesses to reduce transportation services to the entire public, especially to those residing in rural areas. Advocacy also suggested that a service-based alternative to the proposed rule would provide better long- and short-term transportation to all passengers, including those with disabilities, and would meet the DOT's goals.

DOT staff and representatives of the affected small businesses met to discuss the regulation and its alternative, an important step in the DOT's RFA analysis. The meeting provided a meaningful opportunity for small businesses to discuss cost projections and other relevant data related to the proposed rule. After carefully studying the entire public docket that included the information provided by small businesses, the DOT in September 1998 published a final rule adopting an innovative approach recommended by small bus operators. The revised rule not only achieved the agency's objectives, but also struck a sensible balance among all public policy concerns raised during the public review period. Essentially, DOT transitioned the redesign of all buses to accommodate passengers with disabilities while maintaining service for those who rely on small bus companies for essential transportation. Small businesses welcomed DOT's final rule, expected to save the small bus industry about $180 million while guaranteeing transportation for the disabled.

The Small Business Advocacy Review Panel Process Produces Better Regulatory Analyses

One of the more significant provisions of the 1996 SBREFA amendments to the RFA was the establishment of the small business advocacy review panel process. The EPA and OSHA are now required to reach out and include small businesses in the development of regulations.[16] Whenever the administrator of either agency cannot certify under the RFA that a regulatory proposal will not have a significant economic impact on a substantial number of small entities, the SBREFA amendment requires the agency to convene a panel and prepare a regulatory flexibility analysis.

Each panel consists of representatives from the rulemaking agency, the chief counsel for advocacy, and the administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget. The panel conducts its own outreach to small entities likely to be affected by the proposal, seeks their input on the proposed regulation, and prepares a report to the administrator of either the EPA or OSHA with recommendations, where appropriate and equitable, for reducing the potential impact of the rule on small businesses. The panel, which must be convened prior to publication of the proposed rule for public comment, has 60 days in which to prepare and submit the report on its findings to the administrator. The report becomes a part of the public rulemaking record. After the panel's report is received, the agency may reconsider and modify its proposal in response to its economic impact analysis and the information received.

Advocacy's experience in working with panels has demonstrated that the agencies' analytical process has been greatly improved. It is fair to conclude that the panel process has had a salutary effect on the work of the EPA and OSHA, and that the time spent on the panels has been, and continues to be, productive for both agencies and small businesses.

- *The panel process generates better agency analysis.* By collecting and identifying relevant economic data from the regulating agency, the panel process provides an objective basis from which to judge the impact of the regulatory proposal upon small business, the cause and scope of the problems addressed by the proposal, and the comparative contribution to the problem made by different-sized firms within an industry. The quality and extent of discussions generated through the panel process have been invaluable in identifying alternatives for achieving the agency's

16. See generally 5 *U.S.C.* § 609(b)-(e).

statutory objective while minimizing undue costs and burden on small businesses.

- *Direct input from small-entity representatives providing "real world" perspectives is valuable to the panel process.* Small businesses, armed with agency data and analysis at the pre-proposal stage, have an opportunity to provide valuable input on the potential impact of the rule and its design before the agency becomes committed to a particular approach. Their input is particularly useful to the agency because it is based on actual experiences rather than potentially flawed assumptions and cost analyses developed by agency staff in a vacuum. Their input can also help the agency identify alternatives that might accomplish the same policy objectives with much less burden on small businesses.

- *The panel process does not entail any additional agency resources, but uses available resources more efficiently*. Under SBREFA, a panel is convened once an agency determines that a proposed rule is likely to have significant impact on a substantial number of small entities. The RFA already requires the agency to perform a regulatory flexibility analysis once it is determined, at this stage of rulemaking, that there will be such impact. The SBREFA panel approach accomplishes the same objectives by reviewing impact data and alternatives—but in a more structured process that ensures small business input when it matters most. Thus, the panel process marshals the same resources to undertake the same analysis that agencies already are required to do under the RFA and does it within an early timeframe to ensure timely development of a workable proposal. By working with small businesses on the panel early in the rulemaking process, agencies can eliminate problematic provisions before publishing a rule for public comment. This can actually save agencies time and resources that would otherwise be spent on reviewing and responding to written comments.

Environmental Protection Agency Panels

Since SBREFA's enactment, more than 250 small-entity representatives have participated on 15 completed Environmental Protection Agency panels. Each of these panels produced positive outcomes for the EPA and small businesses. In response to small business input, the panels made more than 140 concrete recommendations to the EPA's administrator that address small business concerns without compromising EPA's environmental objectives. When EPA publishes a rule for comment, it explicitly addresses each panel recommendation and makes the panel report part of the public record.

The following EPA rules reviewed by SBREFA panels demonstrate how alternative regulatory measures can indeed be less burdensome on small businesses, at the same time that they are effective in achieving public policy objectives.

Effluent Limitations Guidelines and Pretreatment Standards for the Industrial Laundries Point Source Category. Relying on data from the 1980s, the EPA identified 1,700 industrial laundries as a potential source of hazardous waste solvents discharged to publicly owned treatment works and initiated action in 1992 to address the problem.

Since this rulemaking involved potentially significant economic impacts on a substantial number of small businesses, a panel was convened in June 1997. The panel issued a report in August 1997 making a number of substantive recommendations to the agency, including specific exclusion options for small businesses. The panel recommended that the agency solicit public comment on a “no-regulation” option in the proposed rule. The recommendations were considered and subsequently addressed in the proposed rule, published in December 1997.

Following publication of the proposal, EPA continued to work with the industry, which is dominated by small businesses, and supported the industry's proposal for a strong voluntary pollution prevention program that includes working with the industry's customers to encourage further pollution prevention efforts.

Comments raised by the small-entity representatives during the panel process and by subsequent commenters on the proposal convinced the agency that the industry discharges were not significant enough to warrant national regulation of the entire industry. In July 1999, the EPA withdrew its proposed rule and announced that it would not impose national clean water standards on industrial laundries.

The decision by the agency to select one of the alternative options generated through the panel process as the agency's final decision is a clear demonstration that the process established by SBREFA is effective in producing rational public policy and that consideration of small business impacts need not compromise public policy objectives.

Tier 2 Light-Duty Vehicle and Light-Duty Truck Emission Standards, Heavy-Duty Gasoline Engine Standards, and Gasoline Sulfur Standards. As the EPA took steps to regulate the sulfur content of gasoline in order to enable light-duty vehicles to

lower sulfur emissions, it convened a panel in June 1998. This rulemaking became known as the “Tier 2/Gasoline Sulfur” rule, and the panel completed its report in October 1998.

Panel members visited Frontier Oil Company's refinery in Cheyenne, Wyoming, at the company's invitation. The panel noted that this was a unique opportunity to gain a firsthand perspective on what a small refinery would have to do in order to comply with the rule.

What the panel learned was that the cost of compliance would effectively put small refiners out of business, with a resultant increase in gasoline prices. The panel also learned that the small refiners' product did not contribute significantly to the overall sulfur emission problem that EPA was trying to address.

The panel then considered a wide range of options and regulatory alternatives for providing small businesses with flexibility in complying with potential Tier 2 vehicle emission and gasoline sulfur standards. In response to the comments received, as well as additional business and technical information gathered concerning the affected small entities, the panel ultimately recommended several alternatives. In light of the potentially severe impacts of the regulation on small refiners, the panel agreed on a recommendation to delay application of its rule to small refiners for several years, an option that also met EPA's environmental goals.

In May 1999, the EPA issued its proposed rule based on the panel's recommendation. The EPA's action met with approval from the regulated industries. The proposed rule that resulted from the panel process was clearly an appropriate regulatory solution to achieving the desired environmental results without unnecessarily jeopardizing small refiners, the major source of competition in the industry.

Occupational Safety and Health Administration Panels

Since the 1996 SBREFA amendments to the RFA, OSHA has convened several panels that have submitted reports to the OSHA administrator. The following is a brief description of one OSHA panel that serves as a solid case study on the effectiveness of the panel, not only in analyzing the impact of small entities, but in identifying where conflicting public policies need to be reconciled.

Tuberculosis Exposure. In 1996, the first OSHA panel was convened under SBREFA to consider a proposed rule addressing occupational exposure to tuberculosis (TB). TB

is a disease that afflicts the most vulnerable members of our society—the sick, the poor, the elderly, and the homeless.

In order to control and reduce instances of on-the-job employee exposure to TB, OSHA proposed a series of specific workplace safety requirements for which all employers would be responsible. Specifically, the OSHA proposal required employers to develop and implement a written plan to control worker exposure to TB, comply with detailed requirements for work practice and engineering controls, and keep extensive medical records on employees who may have been exposed to TB. The proposed rule also required employees to use respirators when performing certain job functions or providing patient care.

The fact that potential exposure to TB is most likely to occur, if at all, at very small organizations such as homeless shelters, nursing facilities, home health care units, and clinics raised concerns about the potential significant economic impact of this proposed rule on small entities. Economic analysis indicated that the average cost to comply with this rule for homeless shelters alone would be about $1,000 per year, and the compliance cost for a homeless shelter confronted with an active case of TB would be about $41,000. Hospices, substance abuse treatment centers, and personnel service providers, also very small entities, faced similar and equally devastating compliance costs.

These costs raised the specter that compliance would conflict with equally important public policy objectives—namely, providing shelter for the homeless, dealing with substance abuse, and providing cost-effective services that allow patients to stay at home.

The panel finalized its report in November 1996, and OSHA subsequently published its proposed rule in October 1997. The documentation provided in support of the published proposal indicated that OSHA did take into consideration some of the panel's concerns and adopted some changes from those recommended by the panel, such as clarifying definitions of ambiguous terms. OSHA also agreed to undertake an extensive study on the effects of the rule on nonprofit organizations that provide services to the homeless.

In anticipation of the public comment period on the rule, OSHA staff met with representatives of various small entities that had earlier submitted comments to the panel. As expected, the representatives of homeless shelters, nursing facilities, home health care, and clinics continued to express strong objections to the proposed rule because of

the potential burden imposed on the small entities. Not only did the rule propose requirements that needlessly duplicated local infectious disease control efforts for which small entities are already responsible, but the health care organizations were concerned that OSHA was mandating procedures that might conflict with the provision of medical care.

The entities that would face dramatic impacts from the rule urged OSHA to view this rulemaking in a new light and to consider the practical limitations of the small entities that would be required to comply with the rule. For example, would the hospices, substance abuse centers, and homeless shelters be able to allocate their very limited resources to manage TB exposure through costly engineering controls and patient outplacement? Would the OSHA-mandated controls be enforceable in these workplaces, which are dependent on volunteer workers and charitable financial support, or would the rule simply impose greater compliance and enforcement problems?

They also urged OSHA to consider the possibility that entities that serve high-risk populations may be forced to reduce or eliminate services because of high OSHA compliance costs. By forcing homeless shelters to close their doors because of high costs and potential liabilities imposed upon their volunteer staff, the proposed rule might indirectly cause even greater TB exposure to the society at large by keeping the homeless on the streets rather than in shelters.

OSHA was encouraged to view the issue in a broader context than chiefly workplace safety and to engage both public and private health care specialists in a search for the best approach to controlling the disease overall—to bring conflicting national policies into balance. In thinking "outside the box" from its role as a government regulator, OSHA could serve as a change agent, not only in developing controls that employers could implement in their workplaces but in helping to limit the general public's exposure to TB, work that could be done cooperatively with state and local health care agencies.

As a result of these meetings and discussions, a larger coalition of small and large health care entities, nonprofit service providers, epidemiologists, infectious disease experts, and other health care officials was formed to provide more comments on OSHA's proposed rule.

As of November 1999, OSHA was continuing to review additional public comments before finalizing this rule. It is clear, however, that the SBREFA panel process provid-

ed the critical venue that allowed for more extensive analysis to be received during the regulatory development process.

Judicial Review under SBREFA is an Incentive for Agencies to Comply with the Law

As amended by SBREFA, the RFA now allows courts to review agency compliance with the RFA in appeals from final agency actions.[17] A review of litigation on the RFA over the past three years reveals that small entities are not hesitant to initiate court challenges in appropriate cases. In addition, a significant body of legal precedents has already developed under the RFA, and more cases are sure to arise in the future.

Adding value to the RFA litigation is the role of the chief counsel and the Office of Advocacy. As part of its congressionally mandated responsibilities under the RFA, Advocacy routinely critiques agencies' regulatory proposals and their compliance with the RFA. These communications are a matter of public record that can be used—and have in fact been cited—in judicial appeals. As a result of SBREFA's judicial review amendment, the chief counsel's comments on agencies' regulatory proposals are having greater impact and agencies are now taking them more seriously than ever before.

One agency noted for its RFA reforms is the National Oceanic and Atmospheric Administration's National Marine Fisheries Service (NMFS) within the Department of Commerce, which has defended nine cases or groups of cases brought against the agency. In 1999 testimony before Congress, the NMFS assistant administrator for fisheries readily admitted that "efforts to comply with the Regulatory Flexibility Act, though well intentioned, have not always met with judicial favor. We recognize that there is room for improvement in our economic analyses."[18] If the first step in complying with the law is to identify the problem, then it is clear that agencies such as NMFS have learned from SBREFA that regulations affecting small businesses deserve serious and appropriate analysis.

This was further reinforced by a court decision in a case in which the chief counsel filed the first amicus curiae brief as authorized by the RFA.[19] In *Northwest Mining v. Babbitt*,[20] the District Court for the District of Columbia ruled in favor of small businesses. The

17. *Id.* § 611.
18. *Regulatory Flexibility Act Implementation: Hearings Before the Subcomm. on Fisheries, Conservation, Wildlife and Oceans, Comm. on Resources,* 106th Cong., 1st Sess. (1999) (Statement of Penelope D. Dalton,assistant administrator for fisheries, National Marine Fisheries Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce).
19. 5 *U.S.C.* § 612.
20. 5 F. Supp. 2d 9 (D.D.C. 1998).

case, brought by a trade association against the Department of the Interior's Bureau of Land Management (BLM), raised an issue about BLM's failure to use the proper size standard for determining the number of small businesses that might be harmed by the regulation. In an amicus brief filed in January 1998, the chief counsel challenged the agency's use of a small business size standard that was not in compliance with the SBA's standards published under the authority of the Small Business Act.[21] The brief also raised concerns about the agency's failure to comply with the Administrative Procedure Act[22] and about the quality of the economic analysis put on the record by BLM.

In May 1998, the District Court issued its ruling and agreed with the issues raised by the chief counsel, holding that BLM's certification in its final rule violated the RFA by failing to incorporate the correct definition of "small entity." Accordingly, the Court remanded the case to the agency so that the plaintiff small business trade association would have an opportunity to provide input into the regulatory process.[23]

Filing the *amicus* brief in this case unquestionably increased agency awareness of the risks in failing to comply with the RFA.

In addition to the direct influence that an *amicus* brief can have, as in the above example, even the mere possibility of the chief counsel's intervention in litigation can have tremendous impact on the agency's regulatory process. For example, in the case of *Grand Canyon Air Tour Coalition v. FAA*,[24] the chief counsel filed a "Notice of Intent to File an *Amicus Curiae* Brief." The case involved a DOT, Federal Aviation Administration (FAA) rule that restricted access to the Grand Canyon National Park by small aircraft tour operators. In its RFA analysis, the FAA certified that the rule would not have a significant economic impact on a substantial number of small entities. Yet the proposal applied to an industry dominated by small businesses and limited small business tour operators' access to fly into certain areas, the time for flying, and the frequency of flights. The proposal and its analysis were criticized during the FAA rulemaking process.

In response to the imminent threat of the chief counsel's court intervention, DOT agreed that the FAA would submit to the court a statement detailing its analysis of new data regarding the number of aircraft subject to the regulation, as well as a clear statement that the agency erroneously certified under the RFA that the rule would not have

21. 5 *U.S.C.* § 551 et seq.
22. 5 F. Supp. 2d 9 at 14-15.
23. 332 U.S. Ct. App. D.C. 133 (1998).
24. *Id.* at 154.

a significant economic impact on small businesses. The notice of intent to file the brief was then withdrawn and the court subsequently found that the FAA satisfied the requirements necessary to demonstrate a rational decision-making process as required by the RFA.[25]

Conclusion

Federal agencies have begun to respond positively to the RFA as amended by SBREFA. While some agencies still are not totally in compliance with the law, it is clear that many of them now see the value of the analytical process mandated by the RFA and that the analyses produce better and more informed regulatory decisions. Many have demonstrated that they are more eager than ever before to meet their compliance obligations.

Compliance with the RFA, as amended by SBREFA, can result in a win-win situation for all parties. The DOT rule, the SEC rule on raising capital, the EPA rule on industrial laundries, and the OSHA rule on tuberculosis all demonstrate that less burdensome regulations that minimize economic impact on small business can be equally effective in achieving public policy objectives.

Because of the 1996 SBREFA amendments and diligent oversight and active involvement by Congress, the courts, small businesses, the SBA's Office of Advocacy and the administration, federal agencies are doing a better job of analyzing how best to solve social problems without harming competition or unduly burdening small businesses—the major source of competition and innovation in the U.S. economy.

25. *Id.* at 154.

Appendix E: Regulatory Comments Filed by the Office of Advocacy during Fiscal Year 2000

During fiscal year 2000, Advocacy submitted 79 comments to various agencies and entities. The subject matter of each regulatory action is described briefly below. For more details on the issue, including any related Federal Register references, or to review Advocacy's comments in their entirety, visit Advocacy's website at: www.sba.gov/advo/laws/comments/.

Date	Agency	Comment Subject
10/04/99	FCC	Part 15 spread spectrum devices
10/08/99	FTC	Proposed mergers in the oil industry
10/13/99	ICANN	Uniform dispute resolution policy
10/18/99	FCC	Wireless medical telemetry service
10/20/99	USPS	Delivery of mail to commercial mail receiving agencies
10/22/99	FCC	FCC's compliance with RFA
10/27/99	ICANN	Request for a procedural policy
11/05/99	EPA	Class V underground injection control wells (safe drinking water)
11/08/99	GSA	Contractor responsibility and labor relations cost
11/09/99	ATF	Increase on tobacco products and cigarette papers and tubes
11/09/99	EPA	Pesticides and tolerance processes
11/09/99	FCC	Extending wireless telecommunications services to tribal lands
11/16/99	ATF	Prohibition of certain alcohol containers and standards of fill
11/19/99	OMB	Commercial marine diesel rule
11/22/99	GSA	Federal Supply Schedules for small business opportunities
11/26/99	IRS	Arbitrage restrictions on state/local government tax-exempt bonds
12/08/99	FCC	Rules on 37.0-38.6 GHz and 38.6-40.0 GHz spectrum bands
12/08/99	FCC	Extending wireless telecommunication services to tribal lands
12/09/99	EPA	National emission standards for hazardous air pollutants
12/09/99	FCC	Licensing of fixed services at 24 GHz spectrum band
12/13/99	OMB	Secondary aluminum air toxics standard
12/20/99	FCC	Local competition and broadband reporting
12/20/99	OMB	Special flight rules for commercial air tours in the Grand Canyon
12/21/99	FCC	Establishment of a Class A television service
01/10/00	ICANN	Introduction of new top-level domains to the Internet

Date	Agency	Comment Subject
01/24/00	BLM	Locating, recording, and maintaining mining claims and sites
01/24/00	FCC	Digital audio broadcasting systems
01/31/00	FTC	Consent agreement in the Exxon-Mobile merger
02/09/00	FDA	Premarket approval of silicone inflatable breast prostheses
02/22/00	FCC	Eligibility requirements for PCS C- and F-Block auctions
02/23/00	BLM	Mining claims under general mining laws
02/25/00	HHS	Standards for privacy of identifiable health information
02/29/00	FCC	Part 15 spread spectrum devices
02/29/00	FDA	New policies under the Prescription Drug Marketing Act of 1987
03/01/00	FCC	Eligibility requirements for PCS C- and F-Block auctions
03/01/00	FDA	Procedures for processing of apple cider
03/02/00	OSHA	Ergonomics safety program
03/17/00	FDA	Violation of the Freedom of Information Act (FOIA)
03/22/00	OMB	Data availability regarding the regulation of radionuclides
03/28/00	FCC	Communications between applicants in spectrum auctions
04/04/00	ICANN	Famous mark protection
04/10/00	FCC	Eligibility requirements for PCS C- and F-Block auctions
04/11/00	EPA	Stage 2 disinfection byproducts
04/12/00	EPA	Control of emissions of hazardous pollutants from motor vehicles
04/12/00	USPS	Delivery of mail to commercial mail receiving agencies
04/14/00	ICANN	Final report on famous mark protection
04/17/00	FCC	Reconsideration of the C-Block Fourth Report and Order
04/25/00	OMB	Heavy-duty engine and vehicle standards and diesel sulfur control
04/26/00	FCC	Rules to govern the 4.9 GHz spectrum auction
04/28/00	HCFA	Medicare program and rural health clinics
05/03/00	OMB	Draft arsenic proposal under the Safe Drinking Water Act
05/12/00	ATBCB	ADA accessibility guidelines for buildings and facilities
05/22/00	FRS	Bank holding companies and change in bank control
05/24/00	FCC	Compatibility of cable systems and consumer elections equipment
05/25/00	EPA	Nitrates enforcement under toxic release inventory requirements
06/22/00	FCC	Installment payment financing for PCS licenses
06/23/00	HCFA	Medicare payment for upgraded durable medical equipment
07/10/00	ICANN	Introduction of new top-level domains to the Internet
07/13/00	HUD	Proposal requiring additional smoke alarms in manufactured homes

Date	Agency	Comment Subject
07/17/00	FS	Roadless area conservation
08/10/00	FDA	Drug products that present difficulties for compounding
08/16/00	ICANN	Scope of small business and the Internet
08/18/00	FCC	Part 15 spread spectrum devices
08/22/00	OMB	Federal Coal Mine Health and Safety Act, Black Lung Benefits Act
08/25/00	EPA	Heavy-duty engine and vehicle standards and diesel sulfur control
08/28/00	FCC	Wireless medical telemetry services
08/29/00	FCC	Communications between applicants in spectrum auctions
08/30/00	GSA	Contractor responsibility and labor relations cost
08/31/00	FCC	Licensing of fixed services at 24 GHz spectrum band
08/31/00	USDA	Fee increases for meat, poultry and egg products inspection
09/07/00	FCC	Narrowband PCS competitive bidding
09/12/00	FCC	Access charge reform, universal service
09/14/00	Congress	Rep. Saxby Chambliss re HCFA's compliance with the RFA
09/15/00	WIPO	Internet domain name process
09/20/00	EPA	Control of emissions of hazardous air pollutants
09/21/00	FAA	Airplanes to carry defibrillators for emergency use on passengers
09/26/00	DOI	Surface coal mining hearings and appeals
09/27/00	HCFA	GAO's report on inherent reasonableness regulation
09/28/00	FWS	Critical habitat designation

Appendix F: Federal Court Decisions Published Since SBREFA Amended the Regulatory Flexibility Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) was signed into law on March 29, 1996. In amending the Regulatory Flexibility Act of 1980 (RFA), SBREFA allowed small businesses, for the first time, to seek judicial review of agency compliance with the RFA. Shortly after this provision of the law became effective, small entities began challenging a wide variety of federal agencies' RFA actions.

In addition to legal challenges brought by small entities since SBREFA was enacted, the Chief Counsel for Advocacy also exercised his right under the RFA to file as *amicus curiae* (friend of the court) brief in RFA cases.

The following chart lists, in chronological order, every known significant court decision dealing with RFA issues that has been published since 1996. A short synopsis of each case follows the chart. While 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 Office of Advocacy. Therefore, the following is compiled from all the information available to the Office of Advocacy, and may not necessarily be a complete listing.

Significant RFA Court Decisions Published since 1996

Case	Citation	Issued	Court
Associated Builders & Contractors, Inc. v. Herman	976 F. Supp. 1 (D.D.C. 1997)	07/23/97	District
Southwestern Pennsylvania Growth Alliance v. Browner	121 F.3d 106 (3d Cir. 1997)	07/28/97	Appeals
Associated Fisheries of Maine, Inc. v. Daley	127 F.3d 104 (1st Cir. 1997)	09/16/97	Appeals
Motor & Equipment Mfrs. Assn v. Nichols	142 F.3d 449 (D.C. Cir. 1998)	04/24/98	Appeals

Case	Citation	Issued	Court
Northwest Mining Assn. v. Babbitt	5 F. Supp. 2d 9 (D.D.C. 1998)	05/13/98	District
ValueVision Intl, Inc., v. FCC	149 F.3d 1204 (D.C. Cir. 1998)	07/24/98	Appeals
Grand Canyon Air Tour Coalition v. FAA	154 F.3d 455 (D.C. Cir. 1998)	09/04/98	Appeals
North Carolina Fisheries Assn. v. Daley	27 F. Supp. 2d 650 (E.D. Va. 1998)	09/28/98	District
Greater Dallas Home Care Alliance v. United States	36 F. Supp. 2d 765 (N.D. Tex. 1999)	02/08/99	District
Tutein v. Daley	43 F. Supp. 2d 113 (D. Mass. 1999)	03/17/99	District
National Propane Gas Assn. v. Dept. of Transportation	43 F. Supp. 2d 665 (N.D. Tex. 1999)	03/17/99	District
Washington v. Daley	173 F.3d 1158 (9th Cir. 1999)	04/02/99	Appeals
American Trucking Assns. v. EPA	175 F.3d 1027 (D.C. Cir. 1999)	05/14/99	Appeals
Southern Offshore Fishing Assn. v. Daley	55 F. Supp. 2d 1336 (M.D. Fla. 1999)	06/30/99	District
Texas Office of Public Utility Counsel v. FCC	183 F.3d 393 (5th Cir. 1999)	07/30/99	Appeals
Alenco Communications, Inc. v. FCC	201 F.3d 608 (5th Cir. 2000)	01/25/00	Appeals
Michigan v. EPA	213 F.3d 663 (D.C. Cir. 2000)	03/03/00	Appeals
American Moving and Storage Assn. v. Dept. of Defense	91 F. Supp. 2d 132 (D.D.C. 2000)	03/29/00	District
Allied Local and Regional Mfrs. Caucus v. EPA	215 F.3d 61 (D.C. Cir. 2000)	06/16/00	Appeals
Transmission Access Policy Study Group v. FERC	225 F.3d 667 (D.C. Cir. 2000)	6/30/00	Appeals
AML Intl., Inc., v. Daley	107 F. Supp. 2d 90 (D. Mass. 2000)	07/28/00	District
Communities for a Great Northwest, Ltd. v. Clinton	112 F. Supp. 2d 29 (D.D.C. 2000)	08/23/00	District
Michigan Dept. of Envtl Quality v. Browner	230 F.3d 181 (6th Cir. 2000)	08/24/00	Appeals
National Assn. of Psychiatric Health Systems v. Shalala	No. CIV.A.99-2025-GK, 2000 WL 1677210 (D.D.C. Sept. 14, 2000)	09/14/00	District
Blue Water Fishermen's Assn. v. Mineta	No. CIV.A.99-2846-RWR, 2000 WL 1610349 (D.D.C.,Sept. 25, 2000)	09/25/00	District

***Southwestern Pennsylvania Growth Alliance v. Browner,* 121 F.3d 106 (3d Cir. 1997).** In 1996, plaintiff petitioned for review of an Environmental Protection Agency (EPA) rule which denied Pennsylvania's request that the EPA redesignate an area to attainment status for ozone, pursuant to the Clean Air Act.

During litigation, an intervening party argued that the EPA's rule denying Pennsylvania's request was invalid because the EPA did not comply with the RFA when it issued a short certification that the rule would not affect a substantial number of small entities. The court concluded that the RFA argument cannot be raised because it was not adequately presented to the EPA during the rulemaking process. The court also ruled, in the alternative, that the RFA argument lacks merit, because EPA's rule sufficiently satisfied the requirements of RFA.

Although the court ruled against the RFA argument, it nevertheless made significant findings relating to SBREFA's retroactive applicability. In light of the recently enacted SBREFA amendments to the RFA, the court had to decide whether it had jurisdiction to hear the RFA argument. The intervenor argued that since SBREFA provided for judicial review of agency action under the RFA, the court had jurisdiction. The EPA argued to the contrary because the agency claimed that it published its rule before the effective date of the SBREFA amendments.

Relying on the Supreme Court's precedent on the question of the temporal reach of new statutes, the court held that the SBREFA amendment entitling small entities to judicial review does not "impair rights a party possessed when he acted, increase a party's liability for past conduct, or impose new duties with respect to transactions always completed." This is because the SBREFA amendment "did not change the substantive RFA requirements that applied to the EPA's promulgation of the final rule." Accordingly, the court held that the intervenor properly filed this matter for judicial review under the new SBREFA provision.

***Associated Fisheries of Maine, Inc., v. Daley,* 127 F.3d 104 (1st Cir. 1997).** In 1996, the National Marine Fisheries Service (NMFS) adopted a rule to eliminate overfishing of certain fish. Although NMFS prepared an IRFA and a FRFA for the rule, the FRFA contained the IRFA with no changes except for answers to the submitted comments. Thus the plaintiff brought suit challenging NMFS' compliance with the RFA.

The court held that the FRFA prepared by NMFS pursuant to the RFA was not inadequate on its face. The court opined that an agency can satisfy provisions of the RFA by setting forth the requirements for the FRFA, as long as it compiles meaningful, easily understood analysis that covers each requisite component dictated by the statute. The end product of this analysis must be made readily available to the public.

The court further stated that the defendant secretary of the U.S. Department of Commerce (DOC) complied with FRFA requirements because the secretary explicitly considered numerous alternatives, exhibited a fair degree of sensitivity concerning the need to alleviate the regulatory burden on small entities within the fishing industry, adopted some salutary measures designed to ease that burden, and satisfactorily explained reasons for rejecting others.

***Motor & Equipment Manufacturers Association v. Nichols*, 142 F.3d 449 (D.C. Cir. 1998).** The plaintiffs represent businesses that manufacture, rebuild, and sell car parts in the automobile "aftermarket." Defendant is EPA's assistant administrator. Plaintiffs challenged the EPA's decision to permit California to enforce its own regulations of the on-board emissions devices pursuant to the Clean Air Act, as well as the EPA's rule deeming compliance with the California diagnostic device regulations to constitute compliance with the federal diagnostic device regulations. Plaintiffs also argued that the EPA failed to comply with the RFA.

In ruling that California's own regulations were sufficient to constitute federal compliance, the EPA had concluded that the rule would not have a significant economic effect on a substantial number of small businesses. Thus, the EPA did not conduct a regulatory flexibility analysis on the rule. In making its determination, however, the EPA considered only the impact of its decision on large- and small-volume automobile manufacturers, which did not include the businesses that the plaintiffs represented. Thus, the plaintiffs asserted that the impact on automobile aftermarkets should have been considered as well.

In its decision, the court disagreed and found that the RFA does not require an analysis in such situations. It stated that an agency is under "no obligation to conduct a small-entity impact analysis of effects on entities which it does not regulate." The court reasoned that, because the rule did not subject any aftermarket businesses to regulation, EPA was not required to conduct analysis on the rule's impact on such businesses.

***ValueVision International, Inc., v. FCC,* 149 F.3d 1204 (D.C. Cir. 1998).** In 1997, 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, plaintiff contended that the FCC violated the RFA in that, while the agency performed an IRFA, it only focused on the effect of the rule on small cable operators. The plaintiff argued that the FCC should have considered the interests of leased access programmers—most of whom were small businesses.

The FCC argued that the plaintiff was barred from raising the RFA issue because it failed to argue the point below. The FCC argued that it did issue 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 ruled that the fact that the FCC addressed the issue of small leased access programmers in its FRFA preserved the question on appeal of whether this discussion was sufficient. The court also held that the FCC fulfilled its obligations under the RFA. It reasoned 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.

The court also found that the FCC's conclusion that the revised rules would have only a "positive" effect on programmers (for various reasons) was sufficient to satisfy the obligations of the RFA. 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."

***Grand Canyon Air Tour Coalition v. FAA*, 154 F.3d 455 (D.C. Cir. 1998).** In 1996, the Federal Aviation Administration (FAA) issued a rule restricting access to the Grand Canyon National Park by small aircraft tour operators. The rule limited tour operators' access to certain areas, the time for flying, and the frequency of flights, but the FAA certified that the rule would not have a significant economic impact on a substantial number of small entities.

The Office of Advocacy had earlier filed comments on the FAA's notice of proposed rulemaking (NPRM). Thus, when the matter went to court, Advocacy filed a "Notice

of Intent to File an *Amicus Curiae* Brief," pursuant to its authority under Section 612(b) of the RFA, to address FAA's noncompliance with the RFA. Advocacy ultimately withdrew this notice in exchange for an agreement with the U.S. Department of Transportation (DOT) that the FAA would submit to the court a statement that the agency erroneously certified the final rule.

The court ultimately 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.

***Washington v. Daley*, 173 F.3d 1158 (9th Cir. 1999).** The State of Washington, Midwater Trawlers Cooperative, and others appealed the district court's dismissal of their petitions seeking to overturn regulations that allocated groundfish catches of whiting off the coast to four northwest Indian tribes. They also sought review of the court's decision to grant summary judgment in favor of the Department of Commerce secretary on the allegations that challenged the secretary's compliance with the Magnuson Fishery Conservation and Management Act, the Endangered Species Act, and the RFA.

The court upheld the lower court's decision. In granting summary judgment on the RFA issue, the district court had found that DOC's decision that the agency action would not have a significant economic impact on a substantial number of small entities was valid. The district court specifically noted that the agency concluded that the 7 percent tribal allocation of whiting would result in a 1-3 percent reduction in annual gross revenue for Midwater. Midwater had argued that the court erred in considering the overall effect on its revenues, rather than the effect only on revenue earned from the sale of whiting. The appeals court found that the RFA only requires an agency to consider the economic effect on the entity, not the effect on revenue earned for a particular harvest.

***American Trucking Associations v. EPA*, 175 F.3d 1027 (D.C. Cir. 1999)**. The Clean Air Act requires EPA to promulgate and periodically revise national ambient air quality standards (NAAQS) for each air pollutant identified by the agency as meeting certain statutory criteria. In 1997, EPA issued rules revising the primary and secondary NAAQS for particulate matter and ozone. At the time of the rulemaking, EPA certified the rule pursuant to the RFA as not having any impact on small entities, based on its

conclusion that small entities were not directly subject to the rule because NAAQS regulate small entities only indirectly through state implementation plans.

Plaintiffs argued that the EPA improperly certified under the RFA, asserting that if the EPA had complied with the RFA, it would likely have promulgated less stringent NAAQS than those actually chosen, which would have reduced the burden upon small entities.

The court ruled that the EPA adequately complied with the RFA when it certified small entities are not subject to the proposed regulation. The court also rejected other arguments raised by the plaintiffs. For example, relying on a letter from Advocacy to the EPA stating that NAAQS do impose requirements upon small entities, the plaintiffs had argued that the court must defer to the SBA's interpretation of the RFA. The court ruled, however, that the SBA "neither administers nor has any policymaking role under the RFA; at most its role is advisory. Therefore, we do not defer to the SBA's interpretation of the RFA."

***Texas Office of Public Utility Counsel v. FCC*, 183 F.3d 393 (5th Cir. 1999).** State agencies and telecommunications service providers challenged various aspects of the universal service order issued by the FCC to implement the Telecommunications Act of 1996, including rules developed to modify the existing system of support for high-cost service areas and creation of new support programs for schools, libraries, and health care facilities. Intervenor American Cable Television Association challenged the FCC for failing to meet the requirements of RFA before promulgating the order. However, since none of the plaintiffs raised the RFA issue, and the FCC did not respond to it, the court did not consider the matter in this case.

***Alenco Communications v. FCC*, 201 F.3d 608 (5th Cir. 2000).** Local exchange carriers serving predominately small towns and rural areas sought review of the FCC's action that made various changes to the universal telecommunications service program. Plaintiffs argued that the FCC failed to comply with the RFA because its FRFA did not meet the requirements of the RFA and the FCC did not perform a full economic analysis of the actions.

Citing Associated Fisheries of Maine v. Daley, 127 F.3d 104 (1st Cir. 1997), the court stated that the RFA was a procedural mandate rather than a substantive one, and that review of an agency's RFA compliance was to determine whether the agency made a reasonable good-faith effort to carry out the mandate of the RFA. The court found that

the FCC's orders contained a substantial discussion, including a reasoned rejection of alternatives, which was all that the RFA required.

Regarding the plaintiffs' claim that the FCC had failed to perform an economic analysis, the court found that the RFA does not require a cost-benefit analysis or economic modeling. It only requires the agency to state the steps it has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes. The court further noted that the RFA specifically states that an agency may provide either a quantifiable or numerical description of the effects of the rule or alternatives or a more descriptive statement if quantification is not practicable or reliable. The court concluded that the FCC had reasonably complied with the requirements of the RFA.

***Michigan v. EPA*, 213 F.3d 663 (D.C. Cir. 2000).** The EPA issued a rule mandating that 22 states revise their state implementation plans (SIPs) to reduce nitrogen oxide emissions (Nox). In promulgating the rule, EPA certified under the RFA that the rule would not have a significant economic impact on a substantial number of small entities. The basis of the certification was that the Nox SIP regulation did not establish requirements applicable to small entities. EPA asserted that since the states establish their own requirements, the states were responsible for determining the impact of the requirements on small entities that they regulate. Plaintiffs asserted that the certification was improper and in violation of the RFA.

The court rejected plaintiffs' argument and found that the SIP regulating Nox does not directly regulate individual sources of emissions. The court concluded, therefore, that the EPA's certification was justified.

***Allied Local and Regional Manufacturers Caucus v. EPA*, 215 F.3d 61 (D.C. Cir. 2000)**. Paint manufacturers and associations of manufacturers and distributors of architectural coatings petitioned for review of EPA's regulations limiting the content of volatile organic compounds (VOCs) in consumer and commercial products such as architectural coatings, including paints. Plaintiffs alleged that EPA failed to comply with the RFA by failing to discuss the economic impact of "stigmatic harm" arising from the agency's suggestion that it may impose more stringent VOCs in the future and asset devaluation, in that the coatings rule allegedly will render existing product formulas valueless.

The court ruled that Section 603 of the RFA, which discusses IRFAs, was not subject to judicial review pursuant to Section 611(c). However, the court did have the jurisdiction to determine whether the agency had met the overall requirement that the decision-making not be arbitrary and capricious. The court found that the EPA examined alternatives to product reformulation when creating regulations limiting content of VOCs in consumer and commercial products, and that its decisions were neither arbitrary nor capricious. The court, therefore, found that EPA had met its challenges under the RFA.

***Transmission Access Policy Study Group v. FERC*, 225 F.3d 667 (D.C. Cir. 2000).** The Federal Energy Regulatory Commission (FERC) issued Orders 888 and 889 in an effort to end discriminatory and anticompetitive practices in the national electricity market and to ensure that electricity customers pay the lowest prices possible. The orders required utilities to provide access to their transmission lines to anyone purchasing or selling electricity in the interstate market on the same terms and conditions as they use their own lines. FERC certified that the rule would not have a significant economic impact on a substantial number of small entities.

Plaintiffs argued that FERC failed to consider the impact of the orders on nonjurisdictional entities that may have to provide open-access transmissions and file open-access tariffs under the orders' reciprocity provisions.

In this case, all the parties agreed that the pre-SBREFA-amended version of the RFA applied to the matter. Under that version of the RFA, the court held that its scope of review was quite narrow, and limited to considering the RFA analysis as part of its overall judgment as to whether a rule is reasonable. Using this standard, the court held that it would not question FERC's decision. FERC had looked at the potential impact of Order 888, and included in the order a provision allowing an exemption from compliance with the reciprocity conditions. The court therefore ruled that nothing in the reciprocity conditions was unreasonable.

***Michigan Department of Environmental Quality v. Browner*, 230 F.3d 181 (6th Cir. 2000).** The Michigan Department of Environmental Quality and a manufacturers' association sought review under the Clean Air Act, disapproving revisions to the state implementation plan. Plaintiffs argued that EPA's rulemaking violated the RFA. However, because the plaintiffs failed to raise the issue during the comment period, the court held that they waived them for the purposes of appellate review.

***Associated Builders & Contractors, Inc., v. Herman,* 976 F. Supp. 1 (D.D.C. 1997).** In 1993, the U.S. Department of Labor (DOL) suspended a revised class of employees called "helpers" on federal construction sites, and reinstated former helper regulations pursuant to a congressional mandate. These regulations expired in April 1996. When DOL did not implement the revised helper regulations after the expiration, the plaintiffs sought to have the agency re-implement and enforce the regulations. The plaintiffs alleged that the failure to implement the revised regulations violated the APA, the Davis-Bacon Act, the Unfunded Mandates Act, and the RFA.

DOL had earlier certified under the RFA that its rule would not have a significant economic impact on a substantial number of small entities. Although the agency did not prepare a FRFA, the court held that DOL had met the requirements of the RFA because it had published a certification in the *Federal Register* along with an adequate factual basis.

***Northwest Mining Association v. Babbitt,* 5 F. Supp. 2d 9 (D.D.C. 1998).** In 1997, a coalition of small businesses challenged the Bureau of Land Management (BLM) for failing to comply with the RFA, the Small Business Act, and the APA, in promulgating a rule that would require bonding for businesses and individuals with mining rights. The rule was finalized nearly six years after it was proposed. 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. BLM certified under the RFA 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 businesses.

In January 1998, Advocacy filed its first ever *amicus curiae* brief in court, challenging BLM's use of a small business size standard that was not in compliance with the SBA's size standards published in compliance with the Small Business Act. The brief also raised concerns about BLM's failure to comply with the APA and the substance of the economic analysis put on the record by the BLM.

In its decision, the court agreed with Advocacy's position and found that BLM had not complied with the RFA. The court held that the rule's certification violated the RFA by failing to incorporate a correct definition of "small entity." In remanding the rule to the agency, the court reaffirmed the importance of RFA compliance by stating: "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."

***North Carolina Fisheries Association, Inc., v. Daley*, 27 F. Supp. 2d 650 (E.D. Va. 1998).** In setting its 1997 quota for flounder fishing, the NMFS continued the quota from the previous year. But in doing so, the NMFS did not perform a regulatory flexibility analysis. Instead, the agency certified that the rule would not have a significant impact on a substantial number of small businesses because the quota remained the same from 1996 to 1997. However, there was no indication in the record that the NMFS conducted any comparison of the conditions in 1996 and 1997.

The court remanded the quota to DOC, NMFS' parent agency, after finding that DOC violated the RFA and failed to provide an economic analysis sufficient to comply with National Standard 8 of the Magnuson-Stevens Act. The court ruled that DOC failed to provide a proper factual statement to support its certification, and ordered the agency to undertake enough analysis to determine whether the quota had a significant economic impact on the North Carolina fishery. On remand, the court granted the plaintiffs' renewed motion for summary judgment and found that DOC "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." The court then set aside the quota and imposed a penalty against the NMFS.

***Greater Dallas Home Care Alliance v. United States*, 36 F. Supp. 2d 765 (N.D. Tex. 1999).** In 1998, the plaintiffs sought a preliminary injunction alleging that Congress had acted irrationally and unconstitutionally in passing those portions of the Balanced Budget Act of 1997 which changed the method of payment and reimbursement to home health care providers. The plaintiffs further alleged that the Health Care Financing Administration (HCFA) failed to comply with the RFA in implementing the legislation 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.

In June 1998, the court denied the plaintiffs' request for preliminary injunction and ruled that HCFA acted properly. On the RFA issue, the court stated that because the

underlying statute set forth in detail the formula for the new cost limit, it found that HCFA was merely implementing Congress' directives and was, therefore, not required to conduct a regulatory flexibility analysis.

In a subsequent motion to reopen the case, the plaintiff sought to include a letter written by Advocacy, dated June 15, 1998, as new evidence. Advocacy's letter had 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 hearing already held. The court also found that, even if the letter contained factual information, it was cumulative and duplicative of evidence presented by witnesses, and that 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 in opposition. In February 1999, the court dismissed the entire proceeding.

***Tutein v. Daley*, 43 F. Supp. 2d 113 (D. Mass. 1999).** In 1998, New England commercial fishermen of Atlantic bluefin tuna filed suit against the DOC secretary, asserting that the secretary acted in an arbitrary and capricious manner in issuing an advisory guideline for defining "overfished," and by declaring the Atlantic bluefin tuna overfished based on stock size rather that fish mortality rates. In addition to the plaintiffs' arguments under the Magnuson Fishery Conservation and Management Act, they also claimed that the secretary violated the RFA by failing to prepare a regulatory flexibility analysis for the guideline. DOC had certified under the RFA that the guideline would not have a significant impact upon a substantial number of small entities.

The court dismissed one of the plaintiffs' counts by ruling that Congress did not intend to allow for judicial review of an advisory guideline under the APA and the Magnuson Act. As for the RFA argument, the court deferred its ruling by accepting the agency's argument that the issue is not ripe for decision by the court at this time. The court did find that the issue could be reviewed within the fisheries management program and the implementation of final regulations for consistency with national standards and other laws such as the RFA.

***National Propane Gas Association v. Department of Transportation*, 43 F. Supp. 2d 665 (N.D. Tex. 1999).** In 1997, DOT's Research and Special Programs Administration (RSPA) instituted an emergency interim final rule to address concerns about the transportation of compressed gas on highways. RSPA later modified and adopted the interim

final rule as the emergency discharge control regulation for loading or unloading of cargo tank motor vehicles. The regulation required vehicle operators to shut down immediately if they learned of a gas leakage.

Gas companies brought suit alleging various violations of the APA and RFA. Plaintiffs challenged the rule on the ground that defendants failed to prepare a FRFA as required by the RFA. The agency argued that the rule was not subject to RFA because the law applies only to rules for which an agency is required to publish an NPRM pursuant to the APA. RSPA asserted that an NPRM was not required here because of the emergency nature of the rule. Nevertheless, RSPA claimed that in preparing preliminary and final regulatory evaluations under Executive Order 12866, the agency did analyze the impact of the interim final rule and the final rule on all affected parties, including small businesses.

The court agreed, and found that although the agency did not prepare a FRFA, all of the elements of a FRFA were available throughout their summary of such analysis published in the *Federal Register*. Based on this interpretation, the court found that RSPA complied with each of the requirements of the RFA, including responding to comments and consideration of alternatives. The court asserted that a preliminary regulatory evaluation was available in the docket for the public to provide comment, and it also found that to require an additional analysis by the agency would be duplicative.

***Southern Offshore Fishing Association v. Daley*, 55 F. Supp. 2d 1336 (M.D. Fla. 1999).** In May 1997, the plaintiff brought suit against the DOC secretary, challenging commercial harvest quotas for Atlantic sharks pursuant to judicial review provisions of the Magnuson-Stevens Act and the RFA. For the year 1997, NMFS promulgated a 50 percent quota reduction for sharks, which the plaintiff argued would have a significant economic impact on the fisheries. After almost three years of litigation, this matter is still pending, and a federal court in Florida maintains jurisdiction of NMFS actions in this regard.

In 1997, Advocacy filed to intervene as *amicus curiae* in this litigation. Although Advocacy ultimately withdrew from the matter after the Department of Justice stipulated that the standard of review for RFA cases should be "arbitrary and capricious," Advocacy's involvement during the comment period on the agency's proposal was influential in the court's decision. For example, the court noted that the Chief Counsel for Advocacy is the "watchdog of the RFA," and quoted excerpts from Advocacy's comments on the proposed rule as the court chastised NMFS for not complying with the RFA.

In February 1998, the court ruled that DOC was not arbitrary and capricious in its decision to reduce the quota. However, the court found that DOC's certification of "no significant economic impact" and the FRFA failed to meet APA standards and RFA requirements, and remanded the matter to the agency 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.

On remand, the NMFS prepared a draft analysis and published it for public comment, but after reviewing it, Advocacy again concluded that the analysis did not comply with the RFA. The court issued another order in October 1998, critiquing the insufficiency of the court-ordered economic analysis of the effects of the reduction in the shark quota submitted by NMFS. Accordingly, the court appointed a "special master" pursuant to Rule 53 of the *Federal Rules of Civil Procedure* to assist the court in reviewing NMFS' consideration of alternatives. The defendant objected to the special master referral, and requested the court to instead remand the matter again to NMFS for yet further economic analysis. The court denied this request, but, following subsequent requests from the parties, it extended the stay of the special master proceedings through June 1999.

In June 1999, the plaintiff filed a "Notice of Quota Reduction Contrary to Court Order," alerting the court that NMFS had promulgated new regulations, to become effective July 1, 1999, which substantially reduce the Atlantic shark quotas from operative 1997 levels and implement new, more restrictive fish management and counting methods. The court thus issued an order requiring the parties to show cause why "preventative relief and contempt sanctions (including injunctive relief and fines, if appropriate)" should not issue against the defendant agency for its "imminent violation" of the court's earlier orders requiring that the 1997 Atlantic shark quotas be maintained "pending remand and until further order of the Court." Following written responses, the court held a hearing on this new issue. The next day, on June 25, 1999, the plaintiff filed a new lawsuit, challenging the newly issued regulations. This new lawsuit was consolidated with the instant matter.

On this new issue, NMFS took the position that the new regulations are consistent with the court's previous orders because they are merely a required step in the agency's ongoing obligation to manage and preserve fish stocks. The plaintiff argued that the agency cannot effectuate these new regulations until the court relinquished jurisdiction

over the ongoing remand proceedings and entered a final order. The court agreed, and held that NMFS violated both the spirit and letter of the court's earlier rulings in this case by implementing the new regulations. The court then issued an injunction to NMFS from enforcing the new regulations until the agency can establish bona fide compliance with the court's earlier orders.

On October 1, 1999, the special master submitted his findings and recommendations to the court, finding that NMFS' failure to collect meaningful economic data was arbitrary and capricious. Additionally, the special master found that NMFS' failure to give any consideration to alternatives to the quota was a wanton repudiation of the court's instruction on remand, and that the agency's conduct constituted bad faith and a lack of candor to the court. The agency filed objections to these findings.

On March 2, 2000, the court held a hearing to determine whether the special master's findings should be adopted. Subsequent to this hearing, a settlement was reached between the plaintiff and NMFS. While the court has yet to approve the settlement agreement, in November 2000, federal regulators agreed to delay a decision on new shark fishing quotas until after a review of current and future shark stocks by a group of independent scientists.

***American Moving and Storage Association, Inc., v. Department of Defe*nse, 91 F. Supp. 2d 132 (D.D.C. 2000).** The U.S. Department of Defense (DOD) published a notice in the *Federal Register* announcing a significant change in procurement policy regarding its source for distance calculations for payments and audits in its transportation procurement programs from a previously used official mileage table to a new computer software program. Plaintiffs asserted that the change would have a significant economic impact on small carriers, requiring RFA compliance. DOD asserted that the policy change was not a "rule" as defined by the RFA, and therefore, it did not have to comply with the RFA. The court agreed with the agency and held that the procurement policy change was not a "rule" for RFA purposes. As a result, the RFA did not apply.

***AML International, Inc., v. Daley*, 107 F. Supp. 2d 90 (D. Mass. 2000).** NMFS implemented a management plan for the spiny dogfish industry that imposed quotas that effectively shut down the industry for the next five years. Plaintiffs asserted that NMFS failed to comply with the RFA because it did not perform a regulatory flexibili-

ty analysis in implementing the interim final rule. Plaintiff also argued that NMFS failed to consider alternatives.

The court found that NMFS had met its RFA obligations because it had published an RFA analysis prior to the final rule. Regarding the argument that NMFS failed to provide adequate notice for the interim final rule, the court found that the agency had good cause for bypassing the notice and comment provisions of the APA. Therefore, NMFS was not required to perform an RFA analysis. The court also found that the consideration of alternatives was sufficient, opining that the agency is not required to address all alternatives, but only the significant ones. The court found that NMFS considered and rejected alternatives because they did not meet the mandate of the Magnuson-Stevens Act nor provide long-term economic benefits greater than those of the proposed action.

Finally, the court found that the RFA must be consistent with the conservation requirements of the Magnuson Act. Accordingly, the requirements of the RFA pertaining to adverse impacts are to be applied to the extent practicable given the conservation objectives of the Magnuson Act.

***Communities for a Great Northwest, Ltd. v. Clinton,* 112 F. Supp. 2d. 29 (D.D.C. 2000).** Agricultural and environmental organizations challenged the validity of a draft environmental impact statement prepared for a federal land management plan. Plaintiffs alleged that the U.S. Department of Agriculture and BLM had violated the APA and the RFA.

The court found that the APA and RFA allow judicial review only of final agency actions. Since a draft environmental impact statement is not a final agency action, the court held that the plaintiffs did not have standing to sue.

***National Association of Psychiatric Health Systems v. Shalala,* No. CIV.A.99-2025-GK, 2000 WL 1677210 (D.D.C. Sept. 14, 2000).** The U.S. Department of Health and Human Services (HHS) promulgated an interim final rule that required a physician or other licensed independent practitioner to evaluate a patient face to face, within one hour after the patient has been placed in restraints or in seclusion. The rule was a condition of participation in the Medicare program. The one-hour rule was not a part of the proposed rulemaking. It was published as a part of the interim final rule without

opportunity for notice and comment.

Private psychiatric hospitals and organizations that represent private psychiatric hospitals and psychiatric units in acute care hospitals challenged the rule. The plaintiffs alleged that HHS failed to comply with the requirements of the APA and the RFA in promulgating the rule. The court found that HHS had complied with the APA, but not the RFA.

Regarding the RFA, HHS certified the rule at the time of the proposal. Plaintiffs did not object to that certification. However, plaintiffs argued that because the final rule was dramatically different from the proposed rule, HHS was required to perform an adequate FRFA or certify that the rule would not have a significant economic impact. Plaintiffs argued that HHS' conclusory statement that it did not "anticipate . . . a substantial economic impact on most Medicare-participating hospitals" did neither. Specifically, plaintiffs argued that HHS had not met the requirements of 604(a)(2),(4), and (5) of the RFA.

Section 604(a)(2) requires an agency to provide comments in response to the IRFA. HHS argued that an IRFA was not needed at the time of the proposed rule because it had certified that there was no significant economic impact. Therefore, HHS argued that there were no IRFA-related issues to be discussed in the FRFA. The court agreed with HHS. Likewise, the court agreed that HHS had met the requirements of Section 604(a)(4) of the RFA, which requires the agency to describe reporting, recordkeeping, or other compliance requirements, and estimate the classes of small entities subject to the requirement and the professional skills necessary for preparation of those requirements.

However, the court found that HHS failed to comply with Section 604(a)(5) of the RFA. This section requires the agency to describe the steps that it has taken to minimize the significant economic impact on small businesses, include a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule, and explain why each of the other significant alternatives was rejected. The court found that since there was no discussion of alternatives, HHS had not met its obligations under the RFA. The court remanded the matter to HHS for completion of a compliant FRFA. However, the rule remained in effect because the plaintiffs were unable to show irreparable harm and that the public interest would be best served by enjoining the enforcement of the rule.

***Blue Water Fisherman's Association v. Mineta*, No. CIV.A.99-2846-RWR, 2000 WL 1610349 (D.D.C. Sept. 25, 2000).** NMFS promulgated the final 1999 fishery management plan for Atlantic tuna, swordfish, and sharks. Plaintiffs asserted that the following provisions of the plan violated the Magnuson-Stevens Act and the RFA: placing limits on the amount of Atlantic bluefin tuna that can be caught and kept per fishing trip; banning of fishing during the month of June; placing annual quotas on blue sharks and subquotas for porbeagle sharks; and requiring all pelagic longline fishers to install a VMS unit on their vessels.

On the RFA claim, plaintiffs argued that NMFS did not prepare an IRFA or FRFA for the pelagic shark quotas and the Atlantic bluefin tuna trip limits. The court dismissed the claim, stating that the record reflected that the IRFA was in the record and the information for the FRFA was included in the final regulatory impact review. The court stated that there was nothing improper about an agency performing its IRFA and FRFA in connection with another regulatory analysis required by law.

Plaintiffs also argued that NMFS failed to define the relevant universe of fishers who depend on revenue only from pelagic shark or Atlantic bluefin tuna. The court found that NMFS identified several different possible universes for sharks and evaluated the impacts on each universe. The court reasoned that since shark permits allow holders to catch pelagic, large, and small coastal sharks, it would be nearly impossible to identify the universe of fishers who catch only pelagic sharks. Likewise, the court found that NMFS identified several relevant universes of fishers that depend on revenue from Atlantic bluefin tuna and evaluated the impact of trip limits on each of those groups.

Moreover, plaintiffs argued that NMFS failed to consider the alternatives that would lessen the impact on fishers. The court disagreed, stating that NMFS did consider alternatives and, in fact, adopted an alternative based in part on plaintiffs' comments. The court further stated that while NMFS clearly did not give in-depth consideration to each alternative, the RFA only requires the agency to consider alternatives that would accomplish the stated objectives to the rule.

Appendix G: Congressional Testimony Presented by the Chief Counsel for Advocacy during Fiscal Year 2000

Testimony of Jere W. Glover, Chief Counsel for Advocacy, U.S. Small Business Administration, before the Committee on Governmental Affairs, United States Senate, October 19, 1999

Good morning, Mr. Chairman and Members of the Committee. My name is Jere W. Glover. I am Chief Counsel for Advocacy with the U.S. Small Business Administration.

The Office of Advocacy was established by Congress 20 years ago as an independent entity to be a spokesperson for small business in the formulation of public policy. The Chief Counsel is, by law, appointed by the President from the private sector and confirmed by the Senate.

I am pleased to appear before this Committee to discuss an issue of extreme significance to small business, namely, regulatory paperwork and reports, and the burdens such mandates impose on small business. Before proceeding, however, please note that my comments are my own and do not necessarily reflect the views of the Administration or the Small Business Administration.

First, let me say that I endorse the concepts incorporated in the legislative proposal sponsored by Senator Voinovich and Senator Lincoln—S.1378. It is very similar to that which I supported in testimony on March 5, 1998, before the Subcommittee on National Economic Growth, Natural Resources, and Regulatory Affairs of the House Committee on Government Reform and Oversight. The current proposal would require:

- Annual publication of paperwork and reporting requirements imposed on small business;
- Waiver of civil fines for first paperwork/reporting violations if corrected within a specified time period, except in certain circumstances where there is an overriding public interest concern; and

- The formation of a task force to study the feasibility of streamlining information collection from small business.

Why do I endorse these concepts? Paperwork and reporting requirements are a major cost problem for small businesses. Small companies do not have specific staff to complete the myriad of reports required by government. Often it is the owner or the CEO who must take on this task, making it a very high cost activity for small business, diverting a valuable resource from running the business to an activity that does not generate revenue or contribute to the firm's output. Despite reduction goals established for federal agencies by the Paperwork Reduction Act, the problem and the burden persist.

There is a “perception” problem, as well as a real one. I think it is fair to say that small businesses live in fear that an inspector or auditor will walk through their doors and find them in violation of some law, imposing penalties that will bankrupt them and wipe out life savings invested in their businesses. Reality? I do not know. The fear, however, is real. This gives added importance to the civil penalty waiver provision in the proposal. Significantly, it would implement a recommendation of the 1995 White House Conference on Small Business to the effect that agencies should not assess civil penalties for first-time violators, where the violation is corrected within a reasonable time. S.1378 adopts this approach for paperwork and reporting requirements that do not involve serious health and safety risks, and it contains other limited exceptions that address overriding public policy concerns. The proposal recognizes an implicit truism, namely that small businesses do not have the resources to track all paperwork requirements and are likely to learn of their legal obligations for the first time when an investigator walks in their door. Since compliance should be our regulatory objective, a waiver for first-time violations makes eminent sense, and, if enacted, it should go a long way toward mitigating current fears.

As for the balance of the proposal, let me review some events which I believe will be helpful to the Subcommittee's deliberations.

Let me start with the 1995 White House Conference on Small Business to which I referred in the preceding discussion of the civil penalty waiver.

About 1800 small business delegates participated in that conference and voted on 60 policy recommendations for administrative and/or legislative action. One of those

recommendations, edited here in the interests of brevity, urged that Congress enact legislation that would require agencies to:

- Simplify language and forms;
- Sunset and reevaluate all regulations every five years with the goal of reducing the paperwork burden by at least 5 percent each year for the next five years;
- Assemble information through a single source on all small business reporting; and
- Eliminate duplicate regulations from multiple government agencies.

If I were permitted editorial license, I would substitute the word "reporting" for the word "regulations" in the last item, an issue I will address later in my testimony. As evidence of the pernicious nature of this issue, I need only remind you that paperwork burdens were also an issue addressed by the 1980 and 1986 White House Conferences on Small Business.

Clearly the proposed legislation addresses almost all the concerns detailed in this recommendation of the White House Conference on Small Business. Moreover, there is statistical information to justify the recommendation.

In the fall of 1995, the Office of Advocacy submitted to Congress: *The Changing Burden of Regulation, Paperwork and Tax Compliance on Small Business: A Report to Congress*. A major resource for that study was another report commissioned by Advocacy, *A Survey of Regulatory Burdens* (research summary attached), authored by Thomas D. Hopkins, Rochester Institute of Technology, a leading researcher in quantifying the impacts of regulations on business, especially small business. In brief, Advocacy reported to Congress that the total regulatory cost projected for 1999 would be $709 billion, with one-third of this cost attributed to "process" costs—primarily paperwork. Advocacy further reported that the average annual cost of regulation, paperwork and tax compliance to small business is 50 percent higher than for large business— actual dollar costs amounting to about $5,000 per employee per year. Keep in mind, however, that this cost is for all regulations, not just paperwork and reporting.

Unlike capital costs, which involve a one-time expenditure, process costs (paperwork) do not go away. They never disappear from the books.

The significance of this annual 50 percent cost differential is that it produces an inequitable cost allocation between small and large firms. This 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. The information about the cost differential in both of these studies should also put to rest the canard that efforts to lessen the burden on small business are tantamount to “special treatment” and, ergo, unfair. Not so. Such efforts merely level the playing field and are sound public policy.

The Paperwork Reduction Act, which in and of itself was a good first start, did not focus on the disproportionate burdens that mandated reports impose on small business. The current proposal provides precisely that focus; the disproportionate costs to small business justify consideration of its provisions. Advocacy's research furnishes a rationale for mandating an analysis of how to simplify paperwork and reporting burdens on small business without sacrificing public policy objectives.

The first step toward simplification and the elimination of duplication is the compilation of the reports small businesses must file. This has never been done. Publication of this information in one place is likely to be a revealing eye-opener. The 1995 White House Conference on Small Business specifically recommended that the federal government publish an inventory of all small business paperwork requirements. Such a publication would achieve two purposes. First, small businesses would be able to find, in one place, a description of all the paperwork requirements they must satisfy. This would be a vast improvement over the current state of affairs, where ignorance of regulations is a significant factor behind small business' first-time violations. It should also help promote compliance, that is, if it is comprehensible and not overwhelming. Second, and perhaps most important, policymakers, both inside and outside the federal government, would have the opportunity to review this inventory and make informed decisions (1) about imposing new requirements, (2) about revising existing requirements or (3) about eliminating duplicative and unnecessary requirements.

The compilation should also help distinguish between requirements imposed by regulation and those imposed by congressional mandate. As you know, this distinction has been an issue in determining how well agencies are doing in achieving the paperwork reduction goals set by the Paperwork Reduction Act. The Administrator of the Office of Information & Regulatory Affairs (OIRA) has testified, as has the General Accounting Office in earlier congressional hearings, that a factor contributing to the failure of agencies to reach goals has been added congressional requirements. The

compilation will be a valuable tool for the work of the proposed task force and help focus discussions on ways to simplify and reduce reporting requirements.

One benefit likely to emerge from such a compilation is better identification of duplication and overlap in reporting. Policy makers will be better able to identify where duplication exists, and, given the right kind of analysis, where there is overlap with other reports. As you know, Advocacy reviews regulatory proposals to assess their impact on small business and to evaluate agency compliance with the Regulatory Flexibility Act. One of its tasks is to comment on the value and usefulness of proposed recordkeeping and reports. We have raised questions about how records will be used either by firms or by the agencies, the frequency of agency review of the data reported, and what decisions will be based on the information collected. On this point, I would like to share with you a very specific example of how regulatory reporting can be "off the mark" in achieving a stated policy objective. I believe the following example will underscore the value of the effort you are considering.

Old Forms Die Hard

Under the Emergency Planning and Community Right-to-Know Act, communities are entitled to information about the storage of hazardous materials in their communities. This information is useful in the event of accidents, for example, so that local officials will know how to deal with such incidents, the nature of the hazards with which they may have to deal, and what precautions to take. The reports mandated by regulation under this law required gas stations with 10,000 pounds of gasoline in underground storage tanks to file reports that they, in fact, store gasoline on their premises. It had never been clear to me how these reports enhance the community's knowledge. Particularly ironic is the fact that the estimated 200,000 gas stations—almost all small businesses—had to submit similar reports to three other state and local entities—800,000 pieces of paper annually, at a minimum, advising public officials that the gas stations have gasoline on their premises! And when they did not, they presumably put out signs saying: "No gas today" Clearly this regulation did not save any trees nor tell the public anything it did not already know.

Advocacy first sought repeal of this requirement in 1987. After 2.5 years of my personal involvement, EPA finally repealed this reporting and paperwork requirement in February of this year. As a result of this repeal, Advocacy estimates that small businesses save over 500,000 hours annually—that is significant paperwork

reduction and cost savings—not counting the agency paperwork storage costs that will be saved!

The agency is also considering additional paperwork relief under the “right-to-know” rule. EPA is further proposing to eliminate reporting by small sand, gravel and rock salt operations and converting to plain English the remaining reporting requirements applicable to storage of chemicals in excess of 10,000 pounds.

This is a major step forward. EPA's action eliminated duplicative reporting, helped small businesses, and did not harm the environment. It is one of the best proposals I have seen. It was worth the 2.5-year wait. But we are still waiting for EPA to provide paperwork relief for small sand, gravel, and rock salt operations!

This brings me to my final issue. It is a topic that I think the proposed task force will be able to address, particularly when armed with the information on the number and kind of reports small businesses must file. As the task force looks to the question of simplification and consolidation of reports, the compilation will demonstrate that some of the same information is repeatedly requested by federal agencies—whether it is IRS, Census, Labor, EPA, or other agencies. However, while each of these agencies may be asking for this information only one time, the small businesses responding to these requests have to provide the same information over and over again to different agencies. With Internet and other new technologies, there is a better way for a small business to provide government agencies with the information they want with minimal burden on the business.

What I envision is a simple electronic form, which I call “Form 1,” that a small business would complete online just one time. The company would input all of its basic essential information there, and then whenever an agency requests information, the business would submit the already-prepared information to the requesting agency through the Internet. Or even better, the business could submit this information a single time to a centralized database, and then, if an agency needs this information, the agency could access the database directly, rather than burden the company again with another request. As I said earlier, most agencies seek very similar, if not the exact same information from companies over and over again. This could be standardized. For agencies requiring additional information not already provided, the company can go ahead and send information without having to submit the entire set of basic

company information again by simply attaching the additional information onto the electronic form that already contains the standard information.

As a prototype on the feasibility of this concept, we are currently working with the Office of Federal Procurement Policy on an initiative to consolidate various paper forms used in seeking government procurement onto a centralized electronic database. With this program, we hope to be able to demonstrate how an electronic process can save both small businesses and government contracting officers valuable time and resources while promoting active participation of small businesses in the federal procurement system.

The concept I laid out is an option that should be explored by the task force. It is within the realm of feasibility, thanks to the availability of advancing Internet technology and the fact that more and more small businesses are utilizing the Internet. This is an idea I have had for some time and I am now convinced that the time is ripe for its implementation. The technology is here, but we need the commitment to make it happen.

In closing, I want to emphasize that the proposal you are considering is conceptually sound and “right on the money.” I cannot address the difficulty or cost of compiling the annual list of reports. If you are told that it will be difficult, that it will be costly, and that it will be burdensome on agencies—this will surely be very clear and demonstrative evidence of the need for this compilation. Such arguments, rather than providing evidence to “deep-six” the proposal, give you even more justification for determining exactly what reports small businesses must file with which agencies. However, this is not my expertise and I am sure others will address that issue. What I do know is that paperwork reduction is no one's priority except small business. Success will come when agencies fully realize how disproportionately small business is burdened by paperwork and reporting requirements and how anti-competitive the costs can be. There are often less burdensome alternatives to help agencies achieve their public policy objectives.

One promising item, the new Administrator of OIRA, John S. Spotila, is someone who knows the small business community well. As former general counsel at SBA he significantly reduced paperwork and SBA's regulations. His recent addition of Ronald Matzner to focus on paperwork reduction exclusively should yield significant results. I am optimistic that real progress can be made and I intend to work closely with them.

Testimony of Jere W. Glover, Chief Counsel for Advocacy, U.S. Small Business Administration, before the Subcommittee on Government Programs and Oversight, Committee on Small Business, U.S. House of Representatives, April 11, 2000

Good morning Mr. Chairman and Members of the Subcommittee. My name is Jere W. Glover, Chief Counsel for Advocacy at the U.S. Small Business Administration. I am pleased to address the issue of e-commerce and the potential for small business. Before proceeding, however, I wish to state that the views expressed here are my own and do not necessarily reflect the views of the Administration or the SBA Administrator.

I would like to lay some foundation before I speak to the issue of particular interest to the Subcommittee.

Congress has struggled for years to determine how to address the problem of regulatory burdens on small business; how to make agencies consider the value of small business to the economy; and how to get agencies to solve public policy issues by getting to the root causes of problems without imposing one-size-fits-all regulatory solutions, but instead customizing solutions that maximize impact and compliance, while minimizing the impact on small business.

Government procurement has been a particularly challenging issue. Congress has rightly been concerned that federal tax dollars be used to get the "best buy," that government manage the procurement process efficiently—meaning at the lowest possible operating cost—and that, at the same time, Congress be assured that tax dollars do not promote industrial concentration, that they do in fact promote competition to ensure lowest costs in the long run. Safeguards were instituted to ensure against abuses such as favoritism in the award of contracts; failure on the part of contracting officers to "shop" the marketplace, etc. Mandates were also established to ensure that small businesses would have some viable access to federal contracting opportunities.

Congressional reforms created a single acquisition regulation, the Federal Acquisition Regulation. Other legislation—the Prompt Payment Act, the Equal Access to Justice Act, and the Competition in Contracting Act—were all enacted in the name of reform, with a view toward ensuring fairness and small business access to government contracting.

Within the past decade, however, the entire procurement process came under criticism for being inefficient—too bureaucratic and too costly from an agency operating cost perspective. Legitimate concerns were raised about so-called cumbersome processes. In response, Congress enacted the Federal Acquisition Streamlining Act, the Federal Acquisition Reform Act, and the Clinger-Cohen Act.

It is perhaps fair to characterize the reform movement of the '80s as an attempt to remove the conditions that had given rise to waste, fraud, and abuse, and that of the '90s as streamlining the acquisition system—pushing the government toward increased use of the Internet and reduced reliance on costly paper acquisition systems.

However, in the push for streamlining, which Advocacy largely supported, Advocacy nevertheless remained concerned that enough safeguards were not built into the reforms. The safeguards we believed were needed were those that would ensure the government continuously shopped for the “best buy”—found most often in the small business sector, the major source of price and quality competition in the economy—and that the vast purchasing power of the U.S. government would not, in effect, end up promoting economic concentration rather than competition. We remained concerned that the reforms advanced in the name of efficiency would result in more bundling of contracts into large contracts on which small businesses could not bid. We also were concerned that contracting officers, being given more discretion in selecting contractors at the same time that the number of contracting officer positions was being reduced, would not have the right incentives to reach out to small businesses on contracts and purchases where small businesses are truly competitive.

Computer technology and the Internet provided an option to help implement operating efficiencies while providing important information on small business capabilities. To reduce search costs, contracting officers needed a service, properly designed, that would make it easy for them to find qualified small businesses. Thus, PRO-Net was developed by the Office of Advocacy. It is a data base that profiles small businesses, providing information on what services and products they offer, their history, etc. Its long-term goal is to be a one-stop information portal on small businesses which all contracting officers—public and private—can consult to find qualified small business vendors. It was a major step toward making it easy for small businesses to do business with all federal agencies (as well as state and local agencies) and to have the data base linked to other federal programs then under development to increase the efficiency of contract management.

But this new Internet-based service could not and was never intended to address all the concerns Advocacy had about the most recent reforms that we suspected would lead to increased contract bundling and the bypassing of small business by contracting officers with impunity.

More than five years have elapsed since the 1994 Federal Acquisition Streamlining Act and we are now beginning to document what has happened. Advocacy contracted for several studies:

- One on contract bundling;
- One on credit card purchases; and
- One on Federal Procurement Center data.

In general, these reports are showing that fewer contracts or fewer contract dollars are going to small business. Let me share with you some data.

Contract Bundling

Advocacy's contractor, Eagle Eye Publishers, Inc., produced data showing that bundling is associated with a decline of dollars to small business. Specifically

- Between fiscal years 1989 and 1997, only 8.9 percent of all prime federal contracts were bundled. That seems like a small number except when one considers that the dollar value of those contracts represented 56.6 percent of all federal prime contract dollars.
- The share of bundled contracts has grown annually since FY 1995 from 9.98 percent in FY 1995 to 12.4 percent in FY 1997.
- Bundling is growing in the construction and other services sector, where there are many small businesses, but appears to be declining in the research and development and supplies and equipment sectors. Where bundling is occurring, it is harming small business.
- The small business share of all federal contacts shrank 1.43 percent between FY 1996 and FY 1998.

Credit Card Purchases

Advocacy has contracted with Eagle Eye Publishers, Inc., to examine data from the Federal Procurement Data Center to see if any determinations can be made as to the number and amount of credit card purchases made with small firms. The data are very preliminary but they show that credit card purchases have increased dramatically, as expected. The total value of purchases made by credit card in FY 1999 was $10 billion. If small business' share remained constant, that would mean $4 billion would

have been spent with small business. Whether or not this is happening is what remains to be documented.

Federal Procurement Center Data

In FY 1998 Advocacy issued a report on data from the federal procurement centers. This report for the first time compiled and published procurement data by individual buying centers and broke down the data on awards to small firms by state and by congressional district. The results were interesting. Overall, two-thirds ($120.2 billion) of the total prime contract dollars were controlled by those centers that spent the least on small firms. These centers spent on average just 6.3 percent of their contract dollars with small firms—a total of only $7.6 billion. More than 10 percent of the centers did no business at all with small business. The FY 1999 report is near completion and there is no reason to believe that much has changed. The basis for our suspicion is that no safeguards, no incentives, and no accountability measures have been put in place to monitor contract awards in advance.

Data tell us that something is wrong but not how to fix the problems. Advocacy makes no claim to hands-on expertise with procurement processes. Nor does it have working knowledge on the day-to-day management of federal contracting. Thus, as is our practice, we convened a meeting of private sector individuals who are conversant with procurement processes and with the world of small businesses trying to do business with the government. The meeting included Dr. Steven Kelman, the former Administrator of the OMB Office of Federal Procurement Policy (OFPP), who has returned to Harvard University after his stint with OFPP. Dr. Kelman, as you know, is the author of many of the procurement reforms adopted to correct inefficiencies in the system.

Drawing on their collective expertise, the group identified several problems that were causing the reduced small business share of federal procurement and the downward trend that would likely continue unless changes were made. Among them:

1. Streamlining rules that give contracting officers significant discretion to deal with large firms, without any built-in small business safeguards;
2. Government-wide agency contracts (GWACs) that bundle, for ease of contract administration, what had previously been individual requests for proposals (RFPs) and contract awards that would, because of their size, effectively preclude small business from competition.

The corrective steps the group believed deserved consideration were as follows:

1. Develop GWACs on which only small businesses can bid and establish GWAC small business goals for each agency.
2. Ensure that all awards—large and small—made to companies on the GSA schedules are reported on an agency's procurement goal reports so that awards to large firms cannot be hidden.
3. Establish blanket purchase agreements (BPAs) for small business, 8(a), SDB and women-owned businesses selected from GSA schedules for various supplies and services and make the BPAs available for government-wide use.
4. Make PRO-Net the central registration for all small businesses.
5. Expand mandatory use of and reliance on PRO-Net to overcome contracting officer inertia in searching for small businesses.
6. Establish interagency surveillance review teams to target procurement centers where awards to small business are declining or nonexistent.
7. Establish a program of monetary incentive awards to program and contracting officers for making awards to small business; and
8. Issue a policy directive to executive branch agencies that urges them to use SBA/OMB contract waiver provisions to award service contracts of less than $100,000 to small businesses.

These recommendations have been forwarded to OFPP and SBA and some steps have been taken. For example, we are working with Deirdre Lee, Director of OFPP, and Sherrye Henry, head of SBA's Office of Women's Business Ownership, to develop a single point of registration for small firms and women-owned firms, which could also become an information site where small firms can find information on all available contracts. PRO-Net could be this site. If this can be accomplished, it will reduce the search costs of finding contract opportunities.

While there are signs of progress, clearly more has to be done to ensure that small business has ready access to federal procurement opportunities and that contracting officers do not overlook the most competitive sector of the economy.

What does this have to do with e-commerce and small business? Let me share with you what we do know. Procurement reforms have led to federal agencies posting business opportunities on the Internet. All federal contractors are now required to transmit invoices electronically. Many federal contractors are also being required to accept contract payments by credit card. The question these changes pose is: how is this affecting small business?

An Advocacy study published in 1999 showed that over 4.5 million small employers used computer equipment in their business in 1998. The percentage of small businesses with access to the Internet nearly doubled from 1996 to 1998 from 21.5 percent to 41.2 percent respectively. However—and this is significant—only 1.4 percent of Internet use among small businesses is directed to e-commerce sales. In addition, this report identified several obstacles facing small business in e-commerce. Costs, security concerns, technical expertise, and customer service were the major roadblocks to greater small business participation in e-commerce. Cost was singled out as the most common and greatest impediment to expanding e-commerce. Three basic cost concerns identified by respondents were: 1) lack of funds for up-front implementation costs; 2) lack of monthly cash flows to maintain their sites; and 3) the probability that there would not be a real return on their investment.

All of these taken together lead us to conclude that without managerial systems in place, or accountability measures that provide incentives for agencies to do business with small business, or services that make it easy for contracting officers to find small business, the benefits of e-commerce as used by the federal procurement system will not redound to small business. Moreover, without such changes, small business will not have the incentive to increase its use of the Internet. There will grow and remain a digital divide—a divide that will be caused in large part by the failure of federal policies to ensure small business access to federal procurement opportunities. E-commerce and the Internet are but tools that without the right building blocks can be used to bypass small business. The building blocks on which the use of technology is grounded are what concern me. Ensuring that the government does business with small business is not dependent on technology. Rather it is dependent on policies and mandates. And it is important to remember that doing business with small business is not social welfare. It is good government and good business. To prove this point I defy anybody to find a $700 toilet seat sold by a small business.

E-commerce is at the center of efficiency reforms in the federal government. It requires business to be computer-oriented. Businesses must know how to navigate the Internet, venture into foreign cyberspaces, transact sensitive and proprietary business on line with limited assurances of privacy protection, avoid cybercrime. But none of this addresses the rules by which contracting officers are to make decisions. Without such rules, small business' share of federal procurement will continue to decline. That is our concern.

A number of the steps we have outlined above are designed to help small business increase its reliance on e-commerce. However, just as PRO-Net was a leap forward, we need new ideas and programs that make it easier for contracting officers to find, select, and award contracts to small business, including women- and minority-owned businesses.

Testimony Submitted for the Record by Jere W. Glover, Chief Counsel for Advocacy, U.S. Small Business Administration, before the Subcommittee on Treasury and General Government, Committee on Appropriations, United States Senate, April 13, 2000

Chairman Campbell, Senator Dorgan and the Members of the Subcommittee:

Introduction and Summary

I am Jere W. Glover and I was appointed by the President and confirmed by the Senate to serve as Chief Counsel for the Office of Advocacy. Our office was created more than 20 years ago to gather information about and represent the interests of small businesses in matters before the executive agencies and Congress. The opinions I express are those of the Office of Advocacy and may not necessarily reflect the opinion of the SBA or any other federal agency.

I regret that I am unable to attend the hearing scheduled for this afternoon before the Subcommittee on Treasury and General Government of the Committee on Appropriations in the Senate. This is a very important hearing on issues important to all small business owners and it is only because I had made a prior commitment to address a large gathering of small business owners in another state that I would miss such an opportunity.

My office has been asked to review a proposal which may be offered by Senator Dorgan called the Fair & Simple Shortcut Tax Plan (FASST). The proposal would dramatically reduce the paperwork and audit anxiety for wage-and-salary-earning taxpayers. In performing his homework and research on the concept, Senator Dorgan provided my office with a copy of the proposal and requested our opinion and our suggestions. We have reviewed the bill and the Office of Advocacy gives it our strong support.

Analysis

Our first concern with any tax proposal is generally how the direct cost is distributed among taxpayers. We need to know how much revenue will be diverted from small businesses and whether those small businesses pay an unfair proportion of the tax. The

FASST proposal should have no impact directly because it adds no new tax to the revenue of small business.

Our next concern is whether or not a proposal imposes an indirect burden on a small business. For example, how much bookkeeping and extra reporting will be required? Are there complex formulas and time-consuming tests? Does the employer have to gather information and turn it over to the federal government in a new and complicated manner? Will the owner probably have to engage skilled assistance and what is the cost? Is the employer required to be the policeman to verify the items that are collected and passed along? Is the act required of small businesses voluntary or mandatory? Is the benefit derived from a changed reporting regime worthy of the burden imposed?

We have reviewed all these questions and asked additional questions of the Senator and his staff before forming our conclusion.

On the “burdens” side, the bill as proposed by Senator Dorgan does impose a slight additional burden on the small business employer. Businesses must present the employee with a slightly longer W-4 form when the employee commences employment or when certain tax-related circumstances change. The employer will have to review the slightly longer W-4 and, using a table provided by the IRS to avoid complicated calculations, will have to withhold a precise amount from the employees' paycheck. Making sure the W-4 is read and applied correctly is important and is an extra burden, although it is not that much out of line with what is currently required. Finally, if the bill becomes law, and employees want to choose the FASST system, the employer must accommodate them and that might mean the owner could be doing two different types of recordkeeping, which might be a burden.

On the “benefits” side of the ledger, the bill has been constructed so that the employee is checking boxes and the employer is reading checked boxes. The amount to be withheld is determined from these boxes and a chart supplied by the IRS, which can be read in a simple and straightforward way. The deductions that are given and the rate of tax applied are static and are not calculated by the business owner. The business owners are not policemen under this proposal and are not liable for inaccuracies in the employee's W-4 declarations. These new procedures were selected for their simplicity and are reasonable and nonintrusive.

As an additional benefit for the business owner, the FASST proposal includes tax credits to defray any extra costs that the proposal may impose. There is a tax credit for 50 percent of the amounts expended in implementing the program up to $1000. There is also a 50 percent credit on costs up to $500 for tax preparation fees if the business sees to it that the information is provided to the government electronically.

We also feel that this proposal provides significant benefits directly to employees and thus would provide a tangential benefit to the small business. We expect employees will be excited to have one flat, reasonable rate of tax. Employees will also be excluded from AMT calculations and retain the benefit of many of the most popular tax deductions and credits. In addition, employees are given a financial incentive to save and invest since a modest amount of investment income will be excluded from tax if the FASST system is used. Last but not least, the most attractive element for employees is electing to enjoy the freedom from filing a tax return and from worrying about an audit. They can participate or not as they wish. These advantages remove another significant element of stress from the working experience of the employees and that will have benefits for the business.

For these reasons, the Office of Advocacy strongly supports the FASST proposal put forward by Senator Dorgan. I would be happy to answer any questions that the Committee might have.

Testimony Submitted for the Record by Jere W. Glover, Chief Counsel for Advocacy, U.S. Small Business Administration, before the Subcommittee on Management, Information and Technology, Committee on Government Reform, U.S. House of Representatives, May 9, 2000

Chairman Horn, Representative Turner and the Members of the Subcommittee:

Introduction and Summary

My name is Jere W. Glover and I was appointed by the President and confirmed by the Senate to serve as Chief Counsel for Advocacy. Our office is located in the Small Business Administration and was created over 20 years ago to gather information about and represent the interests of small businesses in matters before the executive agencies and Congress. The opinions I express are those of the Office of Advocacy and may not necessarily reflect the opinion of the SBA or any other federal agency.

I regret that because of prior commitments, I am unable to attend the hearing personally. This is a very important hearing on issues that touch upon small business access to federal contracting and loans and the impact that tax-related debts have on small businesses. These issues are important to small business owners.

My office has been asked to review H.R. 4181, the Debt Payment Incentive Act of 2000, a proposal to amend the Debt Collection Information Act (DCIA) to include tax indebtedness under its umbrella for the first time. The proposal would allow an agency to prevent the award of a contract to a business that has not paid assessed taxes, interest or penalties. We will limit our remarks to the impact on small businesses and not address the administrative problems for federal agencies, trusting that the agencies can best address whether there is a problem in that area.

The proposed procedure will have some impact on small business, but we feel that any concern can be overcome by:

a. not applying it to simplified acquisitions;

b. having the agency seek the consent of the bidder and review the bidder's records provided by the Treasury Department only after it is clear that the small business is the likely contract winner, rather than before; and

c. allowing a small business 10 days to address the problem unless the business declines to pursue the contract.

Discussion

The fair application of the law is important to small business owners. Small businesses are taxpaying citizens and they believe in fair competition. The vast majority of them do not want other businesses, perhaps less responsible businesses, evading taxes while competing for federal contracts or for any other purpose. Therefore, small businesses would not ordinarily oppose the equal application of tax policies.

However, in practice, this bill will apply only to small businesses. Cash flow is a problem for any business, but the lines of credit used to solve cash flow problems are much more available to large businesses. For small businesses the most prevalent way to solve everyday cash flow problems in today's system (aside from family resources) is the credit card. For a variety of reasons, a credit card is not the best solution for solving tax problems. In a cash crunch, small businesses are left with very limited options to keep the business up and running. Choosing between paying a tax bill and meeting the payroll is often painful.

This is not to say that cash flow problems are unique to small businesses that are poorly run with a bad track record. Cash flow problems can strike any business for a variety of reasons. Even in the federal contracting environment, a contractor or subcontractor cannot always rely on the Prompt Payment Act to work efficiently enough to provide the necessary capital to meet payrolls or pay tax obligations on time. Many federal contracts have progress payments or performance criteria that delay payment pending certain performance benchmarks. Yet benchmarks or not, the small business owner must still meet the payroll; obtain the tools and materials; make timely tax payments, and monthly loan payments. Without a major line of credit to smooth out the peaks and valleys, one interruption in the chain compounds the problem for small businesses. Suppliers might start demanding cash up front for materials needed to start the job. From there, it is a short step to a shortfall on the tax payments. The amendment as proposed could put a small business that is perfectly capable of performing the contract at a tremendous disadvantage compared with a large business with a stronger credit line, even if that large business is not as well qualified to actually perform the work.

One other point: it is always important (and federal policy) to reduce the amount of paper a small business must file to the absolute minimum. The proposed bill would require a new form to be filed by every federal contract bidder—millions of pages of paper. This is a significant increase in paperwork that should be reduced as much as possible. I think we can solve the small business end of this problem by only requiring the form as part of the due diligence from the apparent contract winner.

Suggested Amendments

We believe our concerns about this bill can be resolved with a simple amendment that makes it clear that the procedure does not apply in the case of a purchase under the simplified acquisition procedures (currently purchases under $100,000—we believe that is probably what is intended here anyway). The amendment should also allow a small business 10 days to “perfect” its debt report after receiving notice that the contract would go to the business except that an unfavorable report based on a Treasury inquiry has been received. Granting 10 days moves the responsibility for proceeding with the award of the contract out of the discretion of the contract officer (and the agency) and into the hands of the business owner who can now correct or perfect the report.

If in fact the problem is unpaid taxes, interest, and penalties that have been assessed and remain in arrears, then the business can pay them or work out an agreement with the IRS. The business may even be able to use the pending contract to secure a line of

credit. Even more important, however, is the case where the bad report results from a mistake in the record or a difference of opinion over the nature and amount of the debt. Under such circumstances, the changes we recommend give the small business a chance to present its side of the case to the agency. For example, the business can show that the Treasury computer may not have the latest or most accurate records. It could produce evidence of payment to the IRS or an approved payment plan agreed to by the IRS. Likewise, in a dispute over the amount owed, the business could present mitigating circumstances to the contracting agency that would warrant a waiver in this case.

We hope that this information is helpful to the Committee's consideration. I would be happy to answer any questions that the Committee might have.

Testimony of Jere W. Glover, Chief Counsel for Advocacy, U.S. Small Business Administration, before the Committee on Small Business, U.S. House of Representatives, June 21, 2000

Mr. Chairman, Members of the Committee, my name is Jere W. Glover. I am Chief Counsel for Advocacy at the U.S. Small Business Administration. I was appointed by President Clinton and confirmed by the U.S. Senate in May 1994. I am pleased to have the opportunity to appear before this Committee—the first time in two years—to discuss the Office of Advocacy and to lay before you facts about the policy successes of the office during the six-year period since my confirmation. These successes were made possible in part by actions of the Congress: first, when it established the office in 1976 as an independent voice for small business, with authority to appear as *amicus curiae*, and second, when it enacted the Regulatory Flexibility Act of 1980 (RFA), later amending it with provisions in the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996. Two of the SBREFA amendments are worth highlighting: one reaffirmed the Chief Counsel's right to appear as *amicus curiae* in appeals from agency final actions, expanding the subject matter that the *amicus* could address, and another conferred jurisdiction on the courts to review agency compliance with the RFA.

Before proceeding, it is important to note that my comments reflect my own views as Chief Counsel for Advocacy and do not necessarily reflect the views of the Administration. In the context of this hearing on the independence of the Office of Advocacy, this disclaimer takes on a special significance directly relevant to the issue

before us, namely the independence of the office. Since I assumed the role of Chief Counsel, Advocacy has testified before Congress at least 40 times, and submitted testimony for the record on numerous other occasions. My testimony was never submitted for clearance by any office in the Administration. On 25 occasions I took positions that were not consonant with Administration positions (see attached list). This is some evidence not only of my commitment to small business but of the independence of the office. Independence is a prerogative I have jealously guarded within this office and is also one that has been honored both by the Congress and the Administration.

Independence—How to Measure It

Since assuming office, I have had one objective—to be an independent spokesman for small business before regulatory agencies, before Congress and within the Administration. One example: very early in my tenure as Chief Counsel I openly advocated that the Administration and the Congress establish a procurement goal of 5 percent for women-owned businesses. The Administration eventually adopted this recommendation. Congress also supported it and it has become a vital part of SBA's procurement goal-setting process for agencies.

Significantly, Advocacy has always interpreted its mission broadly. It has filed comments with the Federal Trade Commission on mergers— one affecting small cable companies and another affecting small oil refiners. We also raised small business concerns with the U.S. Postal Service regarding its rule on commercial mail receiving agencies. These actions, we believe, are consistent with the mission given to the office by Congress—that of being an independent voice for small business on all policy issues.

To be an effective voice for small business I have always viewed my role as striving for consensus at both ends of Pennsylvania Avenue. As Committee Members well understand, consensus is not always easily achieved. It can take years, particularly on contentious issues. Witness the time it took to garner support within Congress and the Administration on an amendment that allows the courts to review compliance with the RFA. The issue was first raised during the debates in 1980 over the adoption of the RFA. The issue surfaced again at the 1986 White House Conference on Small Business (WHCSB) convened under the Reagan Administration, and again at the 1995 WHCSB under the Clinton Administration. Judicial review, an issue consistently supported by the Office of Advocacy to the best of my knowledge, became part of the RFA in 1996—four Administrations, nine Congresses, and 16 years after the issue first surfaced.

The key to building consensus is never to view any position taken by the Congress or the Administration or a regulatory agency as cast in stone. The challenge is always to find new arguments and new data in support of reforms and initiatives that help small business. The process is a continuum. At any given moment, you may find the Chief Counsel in disagreement with the Administration and other times in disagreement with Congress, and sometimes with both, for example, on patent and bankruptcy reform. The role of the Chief Counsel is to persist in addressing issues and to bring new data and arguments to the table for consideration by decision makers. Sometimes I have prevailed; sometimes I have not. But I never was pressured, nor did I ever abandon the Chief Counsel's independence to pursue small business issues, even those on which the office did not prevail at a particular point in time.

Thus the question: how is independence measured? Is independence measured by how often the Chief Counsel disagrees publicly with the Administration? Is independence measured by how often the Chief Counsel disagrees with legislative proposals? See again the attached list of those instances in which I have disagreed publicly with the Administration. But it is important to add that public disagreements should not be the norm. Why? Because it serves the interest of small business for the Chief Counsel to be perceived by the Administration, by regulatory agencies and by the Congress as an ally arguing for sound public policy—not as an adversary. Being an ally keeps access to policy councils open to the Chief Counsel. Access to early deliberations is crucial if administrative initiatives are to be tailored to the concerns of small business. Early consultation affords the opportunity to alter proposals, reduces the overall cost of the regulatory process by anticipating and addressing potential objections, and minimizes the cost of the total process up to and including enforcement.

I should further add that anytime the Chief Counsel has to disagree publicly with the Administration (or the Congress), the disagreement must lack acrimony to ensure that the doors remain open to future policy deliberations, often on the same issue. Members of Congress are experts at couching disagreements in diplomatic terms when to do so helps position the debate to garner support at a later date. It is no different for the Chief Counsel working within the Administration or with the Congress.

Finally, while public disagreement with the Administration (or with Congress) may be some visible evidence of independence, it is not the total measure of the Chief Counsel's independence. Other activities should also be part of that measure, to wit,

those occasions when the Chief Counsel has successfully persuaded the Administration to initiate a policy change or to alter a policy it is considering in order to accommodate the interests of small business. To illustrate this point further, it is appropriate to consider the impact on public policy of the White House Conferences on Small Business, where small business people debated an array of topics on which they wanted reform.

1995 White House Conference on Small Business

While I attended the 1980 and the 1986 White House Conferences on Small Business (WHCSB), my involvement with the 1995 WHCSB was as Chief Counsel. The 1,800 small business delegates from the 50 states and U.S. territories adopted 60 recommendations for consideration by both the Congress and the Administration. The Office of Advocacy immediately took steps to implement those recommendations. To do otherwise would have been an abdication of the Chief Counsel's responsibility to represent small business. Some recommendations would require congressional action and others could be implemented administratively. We set up a structure through which we maintained contact with state and issue chairs elected by the delegates to pursue implementation. We held two conferences during which implementation of the recommendations was discussed. We also organized interagency meetings at the White House to discuss administrative measures that should be taken in response to the recommendations. We constructed a directory of delegates by issue and by state for use by the Congress in identifying potential witnesses for legislative hearings. Progress reports were submitted to the Congress, and the President actively sought information during Cabinet meetings on the progress being made by agencies to act on the recommendations.

The record of actions is unprecedented. To date, the number of 1995 Conference recommendations that have resulted in administrative and legislative policy changes exceeds that from any previous conference. Action, in whole or in part, has been taken on nearly every issue recommendation, resulting in significant progress for the small business community.

Through the conference agenda, Congress and the Administration have found common ground on the nation's small business priorities. Congress passed, and President Clinton signed the following legislation in response to the recommendations:

1999

- SBIC Technical Corrections Act
- Small Business Year 2000 Readiness Act

1998

- Internal Revenue Service Restructuring and Reform Act
- Department of Defense Reform Act
- Omnibus Budget Reconciliation Act
- Paperwork Reduction Act Amendments

1997

- Balanced Budget Act
- Taxpayer Relief Act

1996

- Small Business Regulatory Enforcement Fairness Act
- Small Business Job Protection Act
- Health Insurance Portability and Accountability Act
- Economic Growth and Regulatory Paperwork Reduction Act
- Telecommunications Act
- Federal Acquisition Reform Act
- National Securities Markets Improvement Act
- Small Business Programs Improvement Act

1995

- Small Business Lending Enhancement Act

Administratively, the number one priority, clarification of the independent contractor definition for tax purposes, was addressed by the Internal Revenue Service. Working with delegates, the IRS published an agents' field manual that fully explained the agency's policies. Additionally, in the area of pension reform, several administrative changes have led to increased opportunities for small business participation in retirement options (see the following pension discussion).

Other Significant Small Business Initiatives Instituted by the Office of Advocacy

The statute that created the Office of Advocacy (15 *U.S.C.* Sec. 634a *et seq*.) details the responsibilities of the office, which include, among others: examination of the role of small business in the economy; measurement of the direct costs and other effects of regulation; assessment of the impact of the tax structure on small business; study of the ability of the financial markets to meet small business credit needs, including the credit and equity needs of minorities; development of recommendations for creating an environment in which small business can compete effectively, etc. This is an extremely broad mandate and we have worked to ensure that our research addresses emerging

public policy issues that fall within this broad mandate. For example, each year we have published a report ranking all U.S. banks on their lending to small business.

There is one research effort that is worth special mention. Advocacy's research demonstrated that access to equity capita—not merely credit—was becoming a barrier to the growth of small business. The need for equity capital was not being met by the existing venture capital market, which our research documented was investing its resources in much larger investments than small businesses needed. Aggravating the shortfall was the fact that the market for investments between $250,000 and $3 million is disorganized, inefficient and costly to both small firms and “angel” investors. The market needed corrective action. The Office of Advocacy devised an Internet-based system, ACE-Net, through which small firms could list their equity needs, and accredited investors, using a secured password, could access the system to identify firms with which to negotiate an investment agreement off line. The Securities and Exchange Commission (SEC) issued a “no action” letter for the new Internet-based service, and 42 states have adopted an “accredited investor” exemption, several of which are specific to ACE-Net. The SEC recently issued guidance to the effect that for-profit companies using the Internet to list public offerings need to be broker-dealers and comply with all SEC regulations, leaving the field to ACE-Net as a unique service that complies with both federal and state securities laws. Negotiations are now under way to privatize ACE-Net. When this is accomplished, there will have been created a new national market, facilitated by the Internet with the blessings of federal and state regulators, that accredited investors can use to find investment opportunities. This will help close the equity chasm that now exists for small business.

The Internet design for ACE-Net suggested to us yet another application that could help small businesses find procurement opportunities. This evolved into a program called PRO-Net through which small businesses can register their companies, describe their products and services, update their company information at will, and use the service to find procurement opportunities. But the real value of the system is ease of access and reliance on the data by contracting officers to find small businesses with which to explore procurement possibilities. This service is a major step toward eliminating contracting officers' claims that they cannot find small businesses to bid on their requisitions.

These are but two examples of how the Office of Advocacy has both identified and addressed market imperfections that are erecting barriers to the growth and develop-

ment of small business—initiatives that grew out of the very broad mission given to the Office of Advocacy by the Congress.

Small Business Involvement in the Work of Advocacy

The small business public policy issues confronting the Office of Advocacy are as diverse as the industries in which small businesses are engaged, and several would not make headline news in the business sections of our daily newspapers, despite their importance to a particular industry or industries. To stay in touch with changing needs and impacts, and to ensure small business participation in policy deliberations of public officials, Advocacy has done the following:

Held ad hoc industry roundtables frequently with small business representatives to discuss:

- Court decisions on RFA and pending RFA litigation
- Procurement
- Environment
- Workplace safety
- Fishery and other resource regulations (mining, etc.)
- Telecommunications
- Taxes
- Pensions and related issues
- Transportation
- Technology

Government officials, including congressional staff, also attend. The Administrator of OSHA attended one of our roundtables at which the ergonomics rule was discussed. These are important forums where small business owners can meet policymakers face-to-face and engage in two-way communications.

Held regular meetings with leaders of national small business organizations to ensure we remain in touch with the issues of concern to their members.

Direct benefits for small business have resulted. Here is but one example involving the IRS and Treasury. Advocacy has organized dozens of meetings, roundtables and work sessions with IRS and other Treasury officials for small business owners and trade associations. These sessions led to agreements on a simplified defined-benefit plan, safe harbors for small business 401K participation, simplified forms to reduce paperwork burden, and flexibility in participation declarations. We will continue to bring

small business people together with IRS and Treasury officials to discuss continuing concerns on taxes and pensions and we are pleased with the IRS's and Treasury's receptivity to having such meetings.

As for other interactions with small businesses, attached are letters that describe the working relationship Advocacy has maintained with small businesses and their representatives on specific issues.

Beyond our interaction with small firms, the Office of Advocacy has also reached out to academic and government researchers to engage them in dialogues on small business public policy issues. We held a conference on industrial organization economics, examining both the legal and economic trends in this field of research to see what new research was emerging and how court decisions were influencing industrial organization trends. We also sponsored two conferences addressing the impact of bank mergers. The most recent, completed just last week and attended by more than 100 people, produced a wealth of information on what is happening in the banking industry—for example, how small banks are emerging to fill the credit needs of small business, how credit scoring is affecting the market, and how call report and Community Reinvestment Act data can be used to shed light on the credit marketplace. Chairman Leach and Ranking Member LaFalce both addressed the conferees.

Finally, the Office of Advocacy has held three conferences to showcase state and local initiatives that help small business. Discussions on such initiatives help state and local officials institute similar and even improved services for small business. A publication—*Models of Excellence*—emerged from these conferences for use by governors interested in small business initiatives.

Each of these endeavors is premised on a basic economic principle, namely, information rationalizes markets. Markets are imperfect where information is lacking; public policy decisions are also imperfect when they are based on imperfect information. Thus, one of Advocacy's missions is to ensure a place at the table for small business.

Regulatory Achievements—Impact of SBREFA

The foregoing provides a backdrop for Advocacy's important regulatory work. Advocacy reviews and critiques the regulatory proposals of approximately 20 executive branch and independent agencies. The Small Business Regulatory Enforcement Fairness Act, which requires that EPA and OSHA convene small business advocacy

review panels, also mandates that the Chief Counsel be a member of the panel. This change has altered the way these two agencies approach the regulatory process. I have witnessed this change firsthand, having participated in 20 EPA panels and 3 OSHA panels. The work of the panels is labor-intensive, consuming on average over 500 professional hours for Advocacy alone. This average understates the amount of time spent on the OSHA ergonomics rule, especially when one considers the number of meetings Advocacy staff addressed to explain and discuss the rule with small business people. But the effort has been worthwhile, since the panels generated significant savings for small business.

And the impact of SBREFA goes well beyond these two agencies.

When SBREFA was first enacted, the Office of Advocacy provided briefings to approximately 200 small business trade association representatives and more than 500 federal officials. We participated in several meetings convened by the Office of Information and Regulatory Affairs (OIRA) for high-ranking agency officials specifically to discuss the SBREFA amendments, how the amendments would affect their regulatory process, what the law required regarding small business impact analyses and that compliance with the RFA would now be subject to judicial review in any regulatory appeals.

Since then, it is becoming increasingly clear that the SBREFA amendments are changing the culture of regulatory agencies. We documented this trend in last year's report to Congress on agency compliance with the RFA and again in this year's report. That is not to say that all agencies are complying with the RFA 100 percent of the time. That certainly is not the case and we so reported. But there is renewed interest, as reflected in agency concerns about complying with the RFA. We have received a growing number of requests for Advocacy involvement in regulatory deliberations prior to publication of regulations for public comment. And it is also evident from Advocacy's increased involvement with OIRA's review of final rules, pursuant to its authority under EO 12866 and the Paperwork Reduction Act. We believe this change in agency focus is a direct result of the SBREFA amendment that empowers the courts to review agency compliance with the RFA.

It is also a result of the close working relationship SBREFA has in effect established between Advocacy and OIRA in the small business advocacy review panels, which

OSHA and EPA must convene when these agencies anticipate that a rule will have a significant impact on a substantial number of small entities.

Finally, Advocacy's first filing of an *amicus curiae* brief did not go unnoticed. We prevailed on the issues raised in the brief, and the challenged rule was remanded to the agency.

While we have filed only one *amicus curiae* brief, we have nevertheless relied on that authority to resolve several regulatory disputes with agencies. One of the Committee's Counsels has firsthand knowledge of this, since he played a major role in a dispute with the Federal Communications Commission when he was on the staff of the Office of Advocacy. Just four months after I assumed office in 1994, two years before the adoption of SBREFA, we filed a notice to appear as *amicus curiae* in an appeal from an FCC rule. Our notice of intent to file triggered several calls from the commission and the Department of Justice on the issues that concerned us. With only four hours remaining to file the brief, an agreement was reached and a commitment received from the commission to revise the rule along the lines we recommended. The details do not matter—but the process does. This was informal behind-the-scenes negotiation with a regulatory agency on behalf of small business—concrete evidence that the threat of filing an *amicus curiae* brief can be as important as the actual filing. We have found this to be the case in other regulatory disputes that were resolved without Advocacy having to file a brief. By the way, I have with me today a copy of the brief that was never filed.

Impact Measurements

The changes agencies have made to regulatory proposals are further evidence of the cultural change that we believe is occurring. We measure impact not by how many rules we review or how many rules we critique, but by how agencies change their proposals in response to Advocacy's recommendations. The amount of regulatory savings resulting from changes measures Advocacy's impact. We estimate that in FY 1998, changes made to regulatory proposals resulted in $1.5 billion in reduced regulatory savings. In FY 1999, the savings were $5.3 billion. Attached to this testimony is the executive overview of our FY 1999 report to Congress on agency compliance with the RFA, wherein these savings are detailed and documented. Also attached is a graph illustrating these savings. The importance of this report is that it is the first time we have been able to quantify these regulatory savings.

The savings in FY 1999 represent a return of $1,060 for every dollar of Advocacy's budget, which we estimate to be in the vicinity of $5 million, including salaries and

benefits. Having said this, Advocacy recognizes that these savings did not result solely from Advocacy's work. Advocacy partners with small entities, their trade representatives, with OIRA, and, yes, even with regulatory agencies to effect changes in regulations. These savings are the result of these partnerships. And in another sense, these savings also measure increased agency compliance with the RFA.

Committee Questions

This then brings me to the questions raised in your letter of invitation. It also brings me back to the question I raised in the beginning of this testimony: how to measure independence. I have tried to address this issue thus far by describing our work and impact under existing authority. Let me now be more explicit.

In my view, independence cannot and should not be measured by how often the Chief Counsel disagrees publicly either with the Administration or with the Congress. Independence needs to be measured by the totality of the work of the Office of Advocacy on behalf of small business. There will, of course, always be skeptics about the effectiveness of in-house early negotiations on public policy issues, but it is difficult to refute the truism that early access to policy deliberations is the most effective way to influence an outcome. Some negotiations and deliberations are public and produce important changes, as evidenced by meetings we organized for small businesses with IRS and Treasury officials. Others are not but can be equally successful.

Sufficient Independence? Where is the evidence that the office does not have sufficient independence? Where has the office failed to represent small business? I will be the first to admit that we may have missed some regulations and that we have not used our *amicus curiae* authority in every instance where some thought we should. We limit our involvement to those issues where we can make a difference or where small business interests are underrepresented. But this is not a constraint on independence. It is a resource constraint—not a policy or partisan political constraint on the office's independence.

Independent Commission? Should the functions of the Office of Advocacy be transferred to an independent commission? I and my deputy have both worked for two or three collegial bodies in our professional careers and both are of the view that independent commissions are not panaceas for efficient decision-making or for enhancing accountability to the Congress or to the constituencies they serve.

Let's examine the question in the context of the small business advocacy review panel process. Once a panel is convened, it has 60 days to develop a report. This time period is short but helps focus the work of the agency and the panel to bring issues to closure. Often negotiations continue up until the last minute. If a commission has to vote on the report, can the work of the panels be completed within 60 days? If there is a minority opinion by the commission, how will this be addressed? Will the involvement of a commission delay the process and add cost to the work of the panel and the regulatory agency? If the answer to any of these questions is "yes," will this undermine agency commitment to the RFA? And before a panel is convened, will the commission have to vote on the names of the small entities submitted to the convening agency to be consulted by the panel?

Additional questions. Creating an independent entity would clearly alter the working relationship of the commission with regulatory agencies by escalating informal negotiations to formal decision-making on regulatory comments, etc. by the commission. Would early access to policy deliberations be lost since every decision would be subject to a commission vote rather than informal negotiations? How would this alter what is now a cooperative working relationship with nonregulatory agencies such as the Bureau of the Census, which provides data essential to the office's research and regulatory responsibilities? Could debates and votes on commission regulatory comments be sufficiently timely to meet deadlines for public comment? Usually I submit comments and positions to Congress within 24 hours of receipt of the request. Would a commission be able to respond as quickly? As effectively? We think not.

Authority for Agency-Wide RFA Compliance Regulations? Under existing authority, the Office of Advocacy does not have a mandate to promulgate regulations that force compliance with the RFA. GAO has recommended that the office be given such authority. We have issued guidance to agencies on how to comply with the law but have stressed that each agency must rely on the advice of its own general counsels how to mesh compliance with RFA with the diverse array of congressional mandates each agency has to fulfill. I am confident that with existing resources we could not undertake such a comprehensive rulemaking, and I have serious reservations about the wisdom of doing so. Current authority gives the Office of Advocacy and regulatory agencies the flexibility to respond to dynamic changes that are occurring in the small business sector of the economy. The RFA admonishes us to avoid one-size-fits-all

regulations and I have reservations that a one-size-fits-all compliance regulation might also result in harm to small business in the long run.

Conclusion

Before concluding this testimony, I have a few additional questions about the staff's draft of legislation to create an independent commission that deserve some mention. Was there a reason for eliminating the functions

- To study and analyze financial markets?
- To analyze credit and equity availability for minorities as well as to evaluate federal programs to help minority businesses?

Was it merely an oversight that the *amicus curiae* language of SBREFA was not adopted? The SBREFA language strengthened the authority of the Chief Counsel and had been relied on in deliberations with regulatory agencies.

Beyond this, it is important to point out that small business historically has opposed the formation of new bureaucracies, even when the bureaucracy would have helped them. There clearly would be a cost to establishing an independent commission which needs to be considered. The issue of cost is particularly relevant since most of the authority the draft bill proposes to be given to the commission already exists in the Office of Advocacy. (An example is subpoena power. On this point, Advocacy has used its subpoena power on several occasions and has also used the petition provisions of the Administrative Procedure Act to seek regulatory reforms.) Any new authority could be given to the Office of Advocacy with little, if any, budgetary implications.

As I mentioned earlier, constraints on the Office of Advocacy are uniquely resource constraints. When the office was first established in 1976, it was given a line-item budget, including a budget for research. This line item was eliminated in recent years, except for economic research. Another constraint on the work of the office has occurred when the position of Chief Counsel remained vacant for a number of years. These problems are easily fixed by the Congress and I believe Senator Bond's bill addresses both of these concerns.

Thank you for the opportunity to address such important issues that affect small business. I appreciate your concern and interest in the work of the Office of Advocacy, as well as your efforts on behalf of small business. I will be happy to provide any additional information you need.

Questions Submitted in Connection with Proposal on Independent Advocacy Commission by Office of Advocacy, U.S. Small Business Administration

Small Business Committee staff have instructed us that the principal issue before the Committee is what is the ideal structure to ensure the independence of a small business advocacy office.

Efficiency, timeliness and impact also need to be addressed.

First, there is NO IDEAL system. The current objective of the office is to demonstrate and stretch its work to reach its full potential—establishing a standard from which future Chief Counsels cannot deviate but only expand and build upon:

- To use all the tools available to help small business
- To achieve consensus at both ends of Pennsylvania Avenue
- To design solutions to market imperfections
- To help agencies develop "SMART" rules
- To save small business regulatory costs
- To create processes that help small business have direct access to decision makers

Let us attempt to do a side-by-side analysis of how the work is accomplished now as compared to how it would be done with a commission:

- Current staff work with small business on a proposed regulation published in the *Federal Register* with deadlines for public comment—the staff drafts a critique of the regulation—submits it for review—it is reviewed usually within hours—signed and sent to the agency.
- In a commission structure, each commissioner and staff would review the letter-debate ensues—a vote is taken. How much time would be needed for this? Would deadlines be met? Would each commissioner wish to speak with small businesses affected? Probably.
- The commission structure generates a process of delay. It does not have the dynamics to move quickly to decision

Conclusion

How are issues selected? Under the current system, staff does the selection. Would this change under a commission structure? Unlikely, not unless the commission wants to peruse the *Federal Register* each day and select the regulatory proposals staff should work on. Does something get lost under the current system? Probably—we probably

miss some regulations but are not timid in asking agencies to reopen the process when small businesses bring a regulation to our attention. In any event, staff works under general guidance to comment on rules where Advocacy is likely to make a difference or where small business interests are underrepresented or where certain issues need to be emphasized.

What about designing solutions to market imperfections? ACE-Net? Pro-Net? Banking studies? These are all staff functions under the current system and would probably remain a staff function under a commission system. What value is added by having three commissioners?

Organizing conferences such as the White House Conference on Small Business, or the bank merger conferences? This too is a staff function and would remain so under a three-headed commission. What value is added by a three-headed commission?

The ombudsman function is also a staff function and would remain so under a three-headed commission? What is the value added by a three-headed commission?

Finally, the small business advocacy review panels. The work is performed by staff—the panel report is drafted by staff—there are negotiations on the report up to and including the very last hour in order to meet the 60-day time limitation—under a commission structure the deadline could not be met—the time limit would have to be extended—giving rise to agency criticism that the RFA delays and increases the cost of regulation—and they would be right.

Amicus curiae authority has been used to get resolution of regulatory disputes right up to the court house steps—up to the nth hour. Could this be done with a commission requiring a majority vote? Unlikely.

Early consultation with agencies on regulations. This is a staff function now and requests for pre-proposal consultation are on the increase. A commission structure provides no incentive—in fact the opposite dynamic would be created—for agencies to work with Advocacy early to avoid adverse small business impacts.

Accountability? The Chief Counsel is accountable to the President, to the Congress and to the small business community. All three know who is in charge. In a three-headed commission, the majority is in charge and who is that? The decisionmaker shifts

and individual accountability of each commissioner is lost. Under the existing system, you know who to blame and who to praise.

How would the effectiveness of each commissioner be evaluated? At least in the current system, you have an easy target.

Thus, in terms of processing the work—of critiquing regulations—of negotiating solutions—a three-headed commission introduces delay. Delay means opportunities lost to effect change in regulations. Accountability is lost. And based on Advocacy staff's experience with commissions, innovation is also lost.

How would the successes—impacts of the commission—be measured? By the number of votes? By the number of comments submitted? These are activity measures—not impact measures. Advocacy now is measuring its impact by the amount of dollars saved for small business. Is not impact what we want to measure? Is not dollars saved what interests small business?

Is the current system neat and tidy? No. But anyone who has worked at a commission knows how untidy a commission decision process can be. Each commissioner has to justify his/her existence and this often takes the form of second-guessing everything. The current system, imperfect though it may be, works, and that is the ultimate test. Is it perfect? No. Some would differ with some decisions we have made but what makes anyone think there will be no disagreements with the decisions of a three-headed commission? The commission structure offers no guarantees that small business, the Congress or the Administration will always agree with its actions—or its inactions as well. So nothing will be different under a commission structure—the commission structure does nothing to ensure unanimity of agreement—there will always be those who disagree. Disagreements do not measure effectiveness or lack of effectiveness. Effectiveness can only be measured by the totality of performance.

Is the current system independent? Emphatically YES. It is as independent as it can be when it must work toward achieving consensus—toward getting small-business-favorable decisions made by a mixture of policymakers, namely, the Congress, the regulatory agencies, the Administration. It has to work within a political structure representative of and pursuing special interest agendas and to strike a balance that harmonizes those interests. Do we always get our way? No. Do we win some? Yes. The commission

structure adds nothing to this. It will have its failures and its successes. And it has no incentive, nor does it have the structure through which to work at achieving consensus; the dynamic that it introduces is confrontation. Confrontation is not conducive to give-and-take discussions on contentious issues. Nor is it conducive to compromise. But it is conducive to gridlock on those issues where there is not a majority—and also because its role is just to vote on positions and not to negotiate resolutions or be part of the process to achieve consensus.