ENTREPRENEURS AND REGULATORS: INTERNET TECHNOLOGY, AGENCY ESTOPPEL, AND THE BALANCE OF TRUST

*James T. O'Reilly**

This study of small business regulation suggests that Congress should require agencies to offer explanatory advice about agency requirements via the Internet, and that the advice should have an estoppel effect to enable reliance by its users. By expanding upon themes from recent legislation and proposed bills, Congress could speed the shift to more rapid and effective advice. This may help to resolve the constant complaints by smaller businesses about the regulatory burdens imposed by the federal system.

INTRODUCTION 64
I. BARRIERS TO THE INNOVATOR-ENTREPRENEUR . 67
A. FIVE MAIN BARRIERS TO ENTREPRENEURIAL DEVELOPMENT 67
1. *The Information Barrier* 67
2. *The Capital Barrier* 68
3. *The Intellectual Property Barrier* 68
4. *Technical Failure* 69
B. THE REGULATORY BARRIER 69
C. REGULATORY REGIMES RESPOND CHIEFLY TO LARGER FIRMS' INTERESTS 71
D. PROHIBITIVE COSTS OF COMPLIANCE WITH ADMINISTRATIVE REGULATIONS 73
II. HOW AGENCIES HAVE RESPONDED TO THE NEED FOR GREATER FLEXIBILITY IN REGULATING THE INNOVATOR-ENTREPRENEUR 75
A. CARVING OUT EXEMPTIONS BY SIZE OF THE ENTERPRISE 75
B. THE REGULATORY FLEXIBILITY ACT 76
C. EFFECTS OF SBREFA 77
III. RESPONSIVENESS MODELS FOR THE TWENTY-FIRST CENTURY—CREATING THE DUTY TO ASSIST 79

* Visiting Professor of Law, University of Cincinnati College of Law.

A. DEFINING THE SCOPE OF THE DUTY TO ASSIST MODEL 82
1. *Qualified of Conditional Responses* 82
2. *Enforcement Thresholds* 83
3. *Self-Reporting and Immunities* 84
B. ESTOPPEL ELEMENT OF THE DUTY TO ASSIST 85
1. *Why an Estoppel Provision is Needed* 85
2. *Limiting Use of Estoppel to Smaller Innovator-Entrepreneurs Only* 86
3. *Limiting Even The Innovator-Entrepreneur's Use of Estoppel* 86
4. *Limiting the Estoppel Period* 87
IV. ALTERNATIVES TO THE DUTY TO ASSIST MODEL 88
A. THE INTERNET MODEL 88
B. THE OMBUDSMAN MODEL 88
C. ARTIFICIAL INTELLIGENCE MODEL 89
D. DIMINISHED COMPLEXITY OF COMPLIANCE STANDARDS 89
V. ANTICIPATED CRITICISM OF A DUTY TO ASSIST . 90
A. COSTS 90
B. DOES OFFERING ADVICE MAKE ANY DIFFERENCE? ... 92
VI. CONCLUSION 93

INTRODUCTION

Entrepreneurs and government regulators see the world quite differently. Economic progress is a function of growth largely driven by entrepreneurial initiatives. Flexibility and risk are essential components of entrepreneurial success. Yet these traits are also antithetical to what bureaucrats deem necessary to ensure the smooth functioning of federal regulatory machinery because uniformity in handling regulated companies or persons is deemed essential. The economic literature analyzing success among entrepreneurs emphasizes a degree of risk tolerance that would be abhorrent to a career bureaucrat.[1] Entrepreneurs and government regulators also view systems of recognition and rewards quite differently. The reward of being a risk-taking entrepreneur is that one can achieve short-term payouts and possibly capture market share for the longer term against the slower and more cautious competitors, whereas bureaucrats view stability, lack of risk, and long-term predictable outcomes as rewarding.

---

[1] Joshua Ronen, *Some Insights into the Entrepreneurial Process*, *in* ENTREPRENEURSHIP 137, 148 (Joshua Ronen ed., 1983).

This article argues (1) agencies charged with regulating the risks taken by innovator-entrepreneurs should seek specific improvements in their Internet-based responsiveness to the informational guidance needs of those innovators; (2) innovator-entrepreneurs should be granted a limited legal entitlement to rely upon advice received from administrative agencies; and (3) two-way interactive dialogue is the optimal response to the climate of alienation and antipathy that currently seems to exist between regulators and innovator-entrepreneurs.[2] While there are costs to providing these extra services to innovator-entrepreneurs, society will benefit from the expanded economic growth that will ensue once innovator-entrepreneurs are free to develop useful and original new products in a regulatory atmosphere that encourages the efficient dissemination of the information needed to remain in compliance with administrative health and safety standards. In short, building trust between government regulators and innovator-entrepreneurs is worth the investment.

Some entrepreneurs are active business innovators who seek to capitalize on risky opportunities in pursuit of profits from production or trade.[3] This article will focus on this subset of entrepreneurs who are also innovators (as contrasted with those who distribute or sell an existing commodity more efficiently) because, as explained below, due to the nature of the innovator's enterprise, the innovator-entrepreneur testing a new product or idea is more likely to encounter regulatory barriers than entrepreneurs engaged in more traditional methods of production or trade.

One economist has defined the entrepreneurial innovator as "the constant and dynamic innovator, who incessantly seeks new endeavors that involve research and development, market testing, and other uncertainty-reducing activities."[4] The innovator's product idea, implanted in the incubator of a small business, can grow to meet a societal or consumer need. This growth flows from the entrepreneur's willingness to take risks in pursuit of the profitable development of that idea. Innovator risks differ from the conventional entrepreneurial risks of capital assets: conventional entrepreneurial risks are internalized and could result in the bankruptcy of one or more individuals, while innovator risks are often

---

[2] *See id.* at 142 (suggesting that excessive regulation can discourage innovators from pursuing their ideas).

[3] For useful definitions see, e.g., Gary D. Libecap, *Entrepreneurship, Property Rights and Economic Development*, *in* 6 ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION AND ECONOMIC GROWTH 67, 69 (Gary D. Libecap ed., 1993); Albert N. Link, *Entrepreneurship and External Sources of Technology*, *in* 6 ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION AND ECONOMIC GROWTH, *supra*, at 177-78; Steven Hobbs, *Toward a Theory of Law and Entrepreneurship*, 26 CAP. U. L. REV. 241, 282 (1997) (quoting HOWARD H. STEVENSON ET AL., NEW BUSINESS VENTURES AND THE ENTREPRENEUR 16 (2d ed. 1985));.

[4] Ronen, *supra* note 1, at 148.

externalized to include users of the new product or those who depend on the novel service the innovator provides. For example, an AIDS drug developer might invest $500,000 in a clinical study that unfortunately does not validate the drug's effectiveness; this is a conventional business risk. Alternatively, an innovator-entrepreneur might externalize risk by rushing into the sale of an unproven drug that she believes capable of helping AIDS patients but that in fact worsens the health of the majority of paying customers. For purposes of this article we will examine predominantly social regulations of a safety and environmental nature,[5] which are often encountered by the innovator- entrepreneur, rather than economic ratemaking and regulation, which are more widely applicable to all business.[6]

In developing new products or processes, the innovator-entrepreneur often risks potential collision with federal regulators such as the Food and Drug Administration ("FDA"),[7] Occupational Safety and Health Administration ("OSHA"),[8] Consumer Product Safety Commission ("CPSC"),[9] Environmental Protection Agency ("EPA"),[10] etc. The government's role as "gatekeeper," tasked with controlling the safety of products or service providers, is likely to conflict with the innovator's "speed to market" ideal in which the innovator obtains a rapid return on his or her investment by moving quickly from an identified market need to a novel product or service that addresses that need.[11] The ability to

---

[5] The advice function discussed herein pertains to permits, approvals, or exceptions that relate to safety, health, or environmental issues, rather than to the more conventional advice regarding economic regulation such as the Department of Justice Antitrust Division's business review letters. 28 C.F.R. § 50.6 (1999).

[6] While each is a form of government regulation, the innovator is likely to encounter the safety and environmental regulators more frequently, especially through on-site inspections, and this trend accelerates as economic regulation declines in deregulated markets such as airlines and telecommunications. Murray Weidenbaum, *Improving the Public Policy Climate for Midsize Business By Reforming Government, in* 10 ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION AND ECONOMIC GROWTH 1, 7-8 (Gary D. Libecap ed., 1998).

[7] The FDA is the gatekeeper agency for pre-market approval of drugs, medical devices, and other products. *See* 21 U.S.C. § 393 (1994).

[8] The U.S. Department of Labor administers the process of safety standard-setting for workplaces under the Occupational Health & Safety Act of 1970. *See* 29 U.S.C. § 651 (1994).

[9] CPSC regulates an immense variety of consumer products by requiring manufacturers to self-report potential product defects. *See* 15 U.S.C. § 2064(b) (1994).

[10] EPA regulates the facilities of innovator-entrepreneurs in numerous ways including through the Resource Conservation & Recovery Act's controls on hazardous waste generated from manufacturing of products. *See* 42 U.S.C. §§ 6921-39 (1994). However, this article focuses on chemical product development prior to marketing, which is subject to exhaustive regulatory controls under the Toxic Substances Control Act. *See* 15 U.S.C. §§ 2601-29 (1994). EPA also has specific product approval authorities under the Federal Insecticide Fungicide & Rodenticide Act, and numerous other laws with which an innovator must comply as a prerequisite to lawful market entry. *See* 7 U.S.C. §§ 135-36 (1994).

[11] Ronen, *supra* note 1, at 142 (Entrepreneurs are "in a hurry to gain the edge on their possible imitators, launch new products, to carry out new factor combinations."). The FDA's

quickly adjust to changing conditions is imperative to the innovator-entrepreneur's success; yet regulation reduces the entrepreneur's capacity for rapid change.[12] Further, through what some economists have called a systematic manipulation of the regulatory system to constrain innovators, larger companies in competition with the innovator-entrepreneur can use long-settled agency relationships to place even further regulatory constraints on the innovator.[13] Improving the dialogue between regulators and innovator-entrepreneurs would carry the major benefits of, first, improving awareness of expectations on the other side; second, anticipating problems that miscommunication can cause; and third, equalizing the flow of specialized knowledge that presently is so favorable to the larger businesses.

I. BARRIERS TO THE INNOVATOR-ENTREPRENEUR

A. FIVE MAIN BARRIERS TO ENTREPRENEURIAL DEVELOPMENT

At least five barriers confront every aspiring innovator-entrepreneur: information, capital, intellectual property, technical failure, and regulatory constraints. After touching briefly on the first four, this article will address the fifth issue at length.

1. *The Information Barrier*

The innovator-entrepreneur faces an information deficit: How can I best identify and exploit an opportunity? Is my idea for a product or procedure feasible and technically supportable? The entrepreneur cures this information deficit through experimentation, research, failure, and modification, collectively known as the innovator's "sweat equity"[14] in the evolution of the concept into tangible form. But the regulatory requirements of various administrative agencies can create their own information deficits that cannot be altered with "sweat equity;" data developed at the earliest stages must be assembled and recorded in the precise format required by government regulators and "gatekeepers,"

---

historical controls on new drug products are derived from an innovator who erred in rushing a new drug to the market in 1937 without recognizing that its liquid component was fatal if swallowed by humans. *See* CHARLES WESLEY DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT 1316-27 (1938). The resulting tragedy, nearly 100 deaths from ingestion of the new product, led to adoption of the 1938 Food Drug & Cosmetic Act's "new drug approval" processes. *See* 21 U.S.C. § 355 (1994); *see also* DUNN, *supra*.

[12] *See* Ronen, *supra* note 1, at 142 (Entrepreneurs surveyed said they "might never have ventured forth as entrepreneurs if governmental regulation had been excessive at the time.").

[13] *Cf. id.* at 9.

[14] Sweat equity refers to "hard work put into a house, business, etc. to increase its value." WEBSTER'S NEW WORLD DICTIONARY 1352 (3d college ed. 1988); *see also* http://www.sweatequity.com (last visited Feb. 21, 2001) (defining sweat equity as "unreimbursed labor that increases the value of a property or is invested to establish a business or other enterprise").

such as patent examiners and drug reviewers. The law grants administrative agencies great discretion to set uniform norms for both procedural elements of the regulatory process (e.g., manner of information collection and submission), as well as substantive evaluation standards used to assess an innovator's compliance with statutory and regulatory requirements.[15]

2. *The Capital Barrier*

The capital barrier prevents most innovator-entrepreneurs from quickly shifting from a supportable idea to a scaled-up manufacturing system that produces a saleable product. Capital flows in the direction of probable success as a free market chooses which competitors to support. The innovator must create value by demonstrating that the idea will attract purchasers, and that the demand for his or her product justifies a price that will both cover operating expenses and generate a positive cash flow. A sound business plan and adequate financial support suffice to overcome this barrier, at least initially. But government regulation impacts the capital barrier as well by adding costs; the innovator's capital might be drained off in a regulatory agency conflict that bankrupts the smaller enterprise before sales and profits can be achieved.[16]

3. *The Intellectual Property Barrier*

Preserving intellectual property presents the innovator with a third potential barrier to success. Often, the entrepreneur's idea is developed with a trade secret or know-how that will ripen into a patent filing in the future. The profitability of the idea depends on being able to protect the secret, typically by investing in a patent filing, successful prosecution of the patent claims, and litigation resources for its defense against infringing competitors.[17] Larger businesses with sophisticated patent staffs can defeat the innovator who errs along the way. Therefore, a chilling effect exists for the smaller firm entering an area well staked by larger patent holders. For the entrepreneur, exploitation of that commercial idea may become financially unachievable if the rights to practice that invention

---

[15] For example, the FDA has been given virtually unchecked authority to determine when a drug innovator has met the "new drug" standards of effectiveness. *See e.g.*, Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 627 (1973).

[16] For example, government can force disgorgement of profits at a level so large that a company becomes unprofitable - a possible death sentence for firms that do not have diversified product lines. *See* Press Release, U.S. Department of Justice, Abbott Laboratories to Remedy Deficiencies in Medical Diagnostic Devices and Pay $100 Million (Nov. 2, 1999), *available at* http://www.usdoj.gov/opa/pr/1999/November/ 522civ.htm.

[17] *See generally* 1 DONALD CHISUM, CHISUM ON PATENTS (2000).

are claimed by a larger firm and the would-be innovator finds that it must pay license fees to the larger competitor.[18]

4. *Technical Failure*

Risks of technical failure and its adverse consequences, such as personal injuries and contractual damages, pose a fourth challenge to the innovator. True innovations like novel drugs carry unforeseen consequences that only emerge after market entry.[19] If the innovator's widget breaks so easily that dozens of users bring products liability claims, the entrepreneur's capital will be exhausted in defense of liability lawsuits or suits for economic damages from the failure of the product. Small size or lack of experience works against the defendant in a products liability lawsuit.[20] The social policy of protecting consumers by allocating the risk of loss to the manufacturer[21] can override the desirability of encouraging innovative experimentation in complex technological products.

B. THE REGULATORY BARRIER

This article addresses a fifth barrier to the innovator: the demands placed on an entrepreneur by the government regulatory agency acting either as a gatekeeper (regulating pre-market product approval) or as a policing agent (controlling design safety or manufacturing aspects of the product after it has been approved for marketing). Government regulatory policies affect the innovator-entrepreneur's environment in several ways;[22] this article examines the product approval context of regulation in which the gatekeeper function is heavily dependent on clarity of communication between the agency and the regulated product innovator.

Administrative agencies produce new rules and regulations, and enforce existing rules in a uniform manner. This equivalence of treatment among regulated parties benefits risk-averse population groups in society, such as airline passengers who expect a uniformly high level of safety regardless of the size of the vendor or aircraft manufacturer. Uniformity also carries a direct benefit to risk-averse agencies that fear being judicially reversed should they selectively accommodate one regulated

---

18 Assuming that licenses can be negotiated, the price paid to practice the invention under a license may eliminate the cost advantage that the innovative product offered over its rivals.

19 This is the rationale for the products liability doctrine exempting new prescription drugs from strict products liability. *See* RESTATEMENT (THIRD) OF TORTS § 6 cmt. g (1998).

20 *See generally* JAMES O'REILLY, PRODUCT WARNINGS, DEFECTS & HAZARDS §1.01 (2d ed. 1999) (discussing other challenges faced by defendants in products liability suits).

21 *See* RESTATEMENT (THIRD) OF TORTS § 2 cmt. a (1998).

22 *See* Albert Bruno & Tyzoon Tyebjee, *The Environment for Entrepreneurship*, *in* ENCYCLOPEDIA OF ENTREPRENEURSHIP 288, 296 (Calvin Kent, et. al eds., 1982) (discussing regulatory burdens of taxation on entrepreneurs).

person's needs over another.[23] For both reasons, agency managers strive to keep interpretations of their agency's rules reasonably uniform within the bounds of past agency precedents.[24]

But both smaller entrepreneurs and larger, more established firms know that one size does not fit all: flexibility and responsiveness to differing needs are very important to the success of the innovator-entrepreneur. For example, uniformly requiring all production to be in 1,000-unit lots would be unacceptable to the company that supplies ten custom made units per month. In fact, regulatory hurdles that may be easy for larger competitors to surmount can mark the end of the race for the smaller innovator-entrepreneur. Larger, more established companies may enjoy an enhanced ability to obtain requisite licensure, or may secure favorable regulatory treatment by virtue of a past relationship with an administrative agency or the ability to dominate negotiated rulemaking proceedings. As the negotiated rulemaking tool evolves,[25] examination of larger firms' advocacy for more stringent regulations[26] continues to be a theme of the literature addressing the negotiation process, and the wisdom of allowing larger firms to manipulate and control the rulemaking process to the detriment of smaller concerns has been increasingly called into question.[27]

The last decade witnessed a popular backlash against regulatory agencies' perceived inhibitions of new and possibly beneficial drugs, medical devices, consumer safety devices, etc., and resulted in calls for government to reduce barriers to innovation.[28] Despite some progress in

---

[23] Agencies that set preconditions for market entry are particularly concerned with the comparability of their standards across competing product types. *See, e.g.*, Forester v. Consumer Prod. Safety Comm'n, 559 F.2d 774, 792-93 (D.C. Cir. 1977) (divergent treatment of two types of bicycle brakes held irrational).

[24] Failure to do so can lead to years of litigation and saddle agencies with a major burden when they alter their position on a controversial policy. *See e.g.*, Securities & Exch. Comm'n v. Chenery Corp., 332 U.S. 194 (1947) (in which a change in securities regulation triggered litigation that twice made its way to the Supreme Court over a five year period).

[25] Negotiated rulemaking is a structured process for the development of federal agency regulations through the convening of dialogue groups composed of the representatives of the parties most interested in that rule.

[26] For example, major makers of washing machines were criticized for their support of energy regulations on appliance design, favoring a "big government rule because it allows them to scrap a lower-priced item with a higher priced one." Kimberly Schuld, *Call Off the Laundry Cops*, CINCINNATI ENQUIRER, Nov. 21, 2000, at A12.

[27] Some commentators fear the negotiated rulemaking process might give regulated industries too much power over how they themselves are governed. *See* Susan Rose-Ackerman, *Consensus Versus Incentives: A Skeptical Look at Regulatory Negotiation*, 43 DUKE L.J. 1206, 1216-17 (1994); *see also* William Funk, *When Smoke Gets In Your Eyes: Regulatory Negotiation and the Public Interest—EPA's Woodstove Standards*, 18 ENVTL. L. 55, 57 (1987). *But see* Henry Perritt, *Negotiated Rulemaking Before Federal Agencies*, 74 GEO. L.J. 1625 (1986); Philip Harter, *Negotiating Regulations: A Cure for Malaise*, 71 GEO. L.J. 1 (1982).

[28] AIDS drug advocates, in particular, were concerned that decisions on adequate proof of pharmaceutical product effectiveness were inhibiting the marketing clearance of new medi-

reducing or eliminating needlessly sophisticated regulations, in practical terms, innovator-entrepreneurs continue to face a series of regulatory barriers that increase in direct proportion to the social cost of the product's risk and the relevant statute's regulatory complexity. A novel medical device may be wonderful for the surgeon, but its maker must satisfy complicated regulatory prerequisites before marketing can begin.[29] The more intricate the agency scheme of control, the more difficult it will be for a smaller enterprise to master that complexity and deliver its project to the marketplace. The mantra that the law must be uniform frustrates those least equipped to comply with its terms.[30] For example, Boeing builds jet aircraft and employs many persons to understand the requirements of federal aviation rules. A smaller aircraft builder could not expect to compete unless it had the expertise, personnel, and capital to satisfy federal aviation requirements.[31] When the makers of a stick with an electric cord sold it to fishermen as a worm probe intended to shock worms, they did not anticipate complaints that human beings could also be shocked; however, the CPSC challenged this simple product in a complex federal court case.[32] Thus, complexity and difficulty of compliance harbor the real potential to drive the smaller innovator-entrepreneurs out of business.

C. REGULATORY REGIMES RESPOND CHIEFLY TO LARGER FIRMS' INTERESTS

All input in the regulatory policymaking context is not regarded equally. Many federal rules are developed in pre-public discussion stages involving representatives of interested groups or constituents who

---

cations. *See* Carolyn Lochhead, *House Votes to Speed FDA Drug Approval*, S.F. CHRON., Oct. 8, 1997, at A3. FDA responded with regulatory changes and ultimately Congress amended the statute to encourage more rapid approval of drugs for special, critical needs. *See* 21 U.S.C. § 356 (Supp. IV 1998).

29 For example, an artificial jaw implant must continuously meet FDA standards for safety and effectiveness or it can be recalled, banned or seized; a smaller company whose medical device fails may face bankruptcy as well as regulatory problems. *See* In Re Temporomandibular Joint Implants Prod. Liab. Litig., 97 F.3d 1050, 1052-54 (8th Cir. 1996) (The FDA ordered the removal of a jaw implant from the market when it was determined to cause harm to patients. The manufacturer of the device went bankrupt.).

30 For an excellent analysis, *see* Paul Verkuil, *The Regulatory Flexibility Act: A Critical Analysis*, 1982 DUKE L.J. 213, 221-23 (1982).

31 *See* 14 C.F.R. pt. 23 (2000) (discussing aviation parts standards).

32 *See* Consumer Prod. Safety Comm'n v. Dye, Consumer Product Safety Guide (CCH) ¶75,407 (D. Idaho Aug. 31, 1988). The ultimate low-tech product was intended to frighten worms out of holes but the CPSC found it could cause electric shocks to humans. *See id.* Though the company actually won its initial court battle, it lost the war; the CPSC later ordered the company to refrain from manufacturing its product after the company had declared bankruptcy. Press Release, U.S. Consumer Products Safety Commission, P&M Worm Probes Found Hazardous; Electrocution Risk Cited in CPSC Order to Halt Manufacture and Sale of Worm Probes (July 26, 1991), *available at* http://www.cpsc.gov.

have captured the attention of a given regulatory agency.[33] Smaller entrepreneurs unable to "capture" the policy-making apparatus of an administrative body are placed at a distinct disadvantage. Effective participation in the rulemaking process necessitates actual attendance and actual participation in such meetings at the agency's headquarters where policies are determined. Yet, this type of participation is a rare luxury for the smaller business owner.[34]

Rulemaking by federal agencies must allow for public comments,[35] usually written objections or statements of support, concerning a proposed rulemaking. The comment process is well understood by the more sophisticated companies affected by new rules. Larger companies can effectively foreclose opportunities for the innovator-entrepreneur by using their input at the rulemaking stage to encourage the agency to set the norm for compliance at a uniformly high level of sophistication that disadvantages small enterprises. The well-informed interested larger businesses tend to adapt well to new rulemaking projects, seeking exceptions and conditions that accommodate their needs through early input during the rulemaking process.[36] The larger business lobbyist can interact early, win seats on advisory councils, and later fill the rulemaking record with support for a clause or exception that benefits its product. The aphorism that the world is divided into "those that make things happen, those that watch things happen, and those who wonder what happened" plays out in every significant rulemaking dispute. Innovator-entrepreneurs tend to be in the latter category because a lack of timely information access frequently denies them access to the rulemaking process.

---

[33] For example, OSHA, within the Department of Labor, uses its National Advisory Commission as a source of comments on its ergonomic regulations. *See* http://www.dol.gov/osha; *see also* E. Donald Elliott, *Reinventing Rulemaking*, 41 DUKE L.J. 1490, 1492-93 (1992), *quoted in* PETER L. STRAUSS ET. AL, ADMINISTRATIVE LAW: CASES AND COMMENTS 337 (9th ed. 1995). Elliott suggests that agencies do not use the notice-and-comment process to obtain public input when making a rule but rather rely upon other means such as "informal meetings with trade associations and other constituteny groups." *Id.* The author writes, "Notice-and-comment rulemaking is to public participation as Japanese Kabuki theater is to human passions–a highly stylized process for displaying in a formal way the essence of something which in real life takes place in other venues." *Id.*

[34] *See* Weidenbaum, *supra* note 6, at 6. The article states:

> It is the rare mid-size company that can afford to detach a member of its management from day-to-day operations for the comparative luxury of attending an academic-like meeting. It is not surprising that, as a result of this neglect, the interests of mid-size companies receive scant attention in the public policy process.

Id.

[35] 5 U.S.C. § 553(c) (1994).

[36] For example, according to the preamble of its final rule on ergonomics, OSHA worked directly with big businesses to reach settlements for ergonomics compliance. *See* OSHA, Ergonomics Program, 65 Fed. Reg. 68,262, 68,264 (Nov. 14, 2000) (to be codified at 29 C.F.R. pt. 1910).

Comments on proposed rules[37] submitted by members of the public were once a valued source of input in the rulemaking process, and the comment period still serves as one of the only opportunities for input available to the smaller innovator-entrepreneur. However, the public's comments have decreased in significance as rulemaking has increased in complexity. The paper flow of the rulemaking comment process has become so unmanageable that agencies have begun to avoid addressing commentators' proposed alternatives. For example, some agencies contract out the handling of comments, and then review only summaries of the major issues raised.[38] Thus, the only method of participation in the rulemaking process the innovator-entrepreneur is likely to have the resources to exploit - the statutorily mandated comment period - is also the method of participation least likely to impact the formulation of administrative rules.

Since innovator-entrepreneurs often lack the resources and entrenched agency relationships necessary to make a difference in shaping administrative regulations, they may often remain uninformed of any new regulations that might govern the development of their ideas until a given rule is published in the Federal Register. Publication in the Federal Register is deemed legal notice to every person of the new rule's requirements,[39] yet few entrepreneurs scour the Register looking for issues that may affect their enterprises. The final rule on design, performance of a product, or process is likely to be comprehensive and precise, but might also be beyond the budget of the smaller entrepreneur.[40]

D. PROHIBITIVE COSTS OF COMPLIANCE WITH ADMINISTRATIVE REGULATIONS

Innovators are less able to amortize the high overhead costs of regulatory compliance across sales volume or over time, because they are likely to lack the capital and personnel needed to satisfy uniform regulatory prerequisites for product manufacture and marketing.[41] Absent the

---

37 For details of the comment process, *see* JAMES T. O'REILLY, ADMINISTRATIVE RULEMAKING, § 5.01 (1983 & 2000 Supp.)

38 The EPA has hired contractors to read incoming comments and produce summaries. *See* EPA, Air and Radiation Docket and Information Center *at* http://www.epa.gov/airprogm/oar/docket.htm (last modified Aug. 16, 1999) (indicating that contract personnel provide the docket services for comments about air rules).

39 *See* Fed. Crop Ins. Corp. v. Merrill, 332 U.S. 380, 384-85 (1947).

40 For example, a critic of FDA radiology equipment rules claimed the rules freeze out small manufacturers of those products by setting the standard for manufacturing plants so high. Kenneth W. Chilton, *Regulation and the Entrepreneurial Environment*, *in* THE ENVIRONMENT FOR ENTREPRENEURSHIP 91, 99 (Calvin A. Kent ed., 1984).

41 For example, small companies lack the depth and extent of staff of the larger companies that routinely deal with FDA approvals, so their innovations are more often brought to market by larger firms. *See* Zoltan J. Acs & David S. Evans, *Entrepreneurship and Small*

ability to complete the complex regulatory paperwork needed to get the product to market,[42] the innovator often must sell the company to a larger firm with the resources needed to secure product approval. Alternatively, the innovator might license away the technology underlying the invention, accepting a licensing fee from a more highly capitalized pharmaceutical or chemical maker who then goes on to develop and market the product.[43] In short, large companies are able to crowd out innovator-entrepreneurs in large part because smaller firms are simply unable to comply with costly administrative regulations on their own. This market concentration could be avoided if agencies promoted less complex and expensive forms of compliance.

Even those innovators fortunate enough to remain alive through the product approval process might eventually be bankrupted due to non-compliance issues. For example, in 1999, a multinational firm that failed to satisfy the FDA's complex manufacturing norms was forced to disgorge $100 million of its profits and to undergo tight federal supervision for at least four years. Should it fail to comply again in the future, additional penalties will be owed to the government.[44]

Thus the conundrum for the small entrepreneurial firm: innovation often starts with a single energetic inventor who wants to bring a fresh, new, and useful idea to market. But the regulated firms who dominate some markets have ramped up the costs of participating in the regulatory approval process, so that the innovator-entrepreneur cannot afford to compete with larger firms in the race for product approval and distribution. As regulations grow more complex, control systems imposed by federal agencies become even more substantial barriers. The quality systems regulations for medical devices,[45] new drug application requirements for pharmaceuticals,[46] and the aviation safety rules of the Federal Aviation Administration[47] illustrate the problem of process standardization set at a level of sophisticated compliance that is likely to exceed the reach of the smaller entities. An economist has shown how "bureaucratic drift" toward more complex and intensive regulation results in approval delays, prohibitive costs, and increasingly intense data development re-

---

Business Growth: A Case Study, *in* 6 ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION AND ECONOMIC GROWTH, *supra* note 3 at 143, 169-70.

[42] *See id.* at 173 (small entities lack specialized personnel and cash flow to attain the level of manufacturing sophistication demanded by regulatory norms).

[43] As an expert witness in pharmaceutical cases, the author has observed that innovators who lack the capability to surmount FDA approval barriers will usually license the product to a firm with extensive product lines, and the new owner takes on responsibility for details of the drug's compliance.

[44] *See* U.S. Dep't of Justice, *supra* note 16.

[45] *See* 21 C.F.R. §§ 820.1-820.250 (2000).

[46] *See id.* §§ 314.1-314.560 (2000).

[47] *See* 14 C.F.R. §§ 21.1-21.621 (2000).

quirements, while procedures and statutes limit any contrary drift toward diminished burdens.[48]

II. HOW AGENCIES HAVE RESPONDED TO THE NEED FOR GREATER FLEXIBILITY IN REGULATING THE INNOVATOR-ENTREPRENEUR

A. CARVING OUT EXEMPTIONS BY SIZE OF THE ENTERPRISE

Of course, society wants and deserves to be protected from harmful products. Legislation empowers various administrative agencies to enforce protective norms so that society can be shielded from the potential harms flowing from large and small sources alike. But the need for uniform protection does not imply that there is only one, uniform way to provide it; the application of alternative compliance procedures for smaller, innovative concerns could protect the public, while simultaneously stimulating creativity and improvements in the marketplace that benefits society as a whole. Congress has responded to smaller business' concerns about the burdens of regulation by creating a series of specific exceptions to various normative regulations. For example, OSHA does not routinely require injury and illness reports from facilities with fewer than ten employees.[49] The EPA does not impose its strict hazardous waste rules upon those who generate only small quantities of waste.[50] The Wage & Hour Division of the Department of Labor treats the smallest employers differently on wages and overtime issues.[51]

Public controversy over these carve-out exceptions varies according to the nature of the basic regulation. For example, an exclusion of a business from the coverage of a health mandate or a safety prerequisite is much more likely to be challenged than a purely economic exception, because jeopardizing the health or safety of even one individual seems unacceptable.[52] Therefore, a normative view of uniform national safety goals argues for rejection of a regulatory carve-out based on the size of an enterprise. After all, the goal of social regulation is to prevent harm,

---

[48] Mary K. Olson, *Explaining Regulatory Behavior in the FDA: Political Control vs. Agency Discretion*, *in* 7 ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION AND ECONOMIC GROWTH 71, 73 (Gary D. Libecap ed., 1996).

[49] 29 C.F.R. § 1904.15 (2000).

[50] 40 C.F.R. § 262.34 (2000).

[51] *See* U.S. Department of Labor, Small Business Handbook, Wage, Hour and Other Workplace Standards, *available at* http://www.dol.gov/dol/asp/public/programs /handbook/minwage.htm (last updated Dec. 1999) (describing an exemption from wage and hour provisions for firms with less than $500,000 in annual dollar volume of business); *see also* 29 C.F.R. § 516 (2000) (exempting certain types of employees in any size business from wage and hour requirements).

[52] For example, OSHA-has indicated that it "does not consider it to be appropriate to determine the extent of protection afforded an employee by the size of the business he/she is employed in." 29 C.F.R. § 1904.15 (2000).

but carve-out rules seem to condone it by permitting more injuries to occur than would be possible under a uniform system of full inspection and enforcement. As to the safety of products prepared at the smaller site, a carve-out would arguably have even less justification because the consumer does not often know the employee size or status of the producer (and therefore, when the carve-out exception applies). Consequently, those who oppose carve-out exceptions may argue that consumer expectations of prophylactic government regulations are frustrated by undisclosed exceptions from regulatory safeguards.

A pragmatic argument in support of carve-out exemptions for smaller innovator-entrepreneurs might assert that, given the limited resources of administrative agencies, safety regulators should aim at the targets where deterrence will produce the greatest quantity of public health protection.[53] For example, since there are a limited number of occupational safety inspectors available, their deployment to larger factories with greater risk potential seems appropriate, even though smaller facilities pose risks as great as the larger factories in some instances. The ultimate decision as to whether or not to permit carve-outs and under what circumstances is a policy choice for Congress to make. As mentioned above, Congress has enacted legislation permitting regulatory carve-out exemptions for smaller enterprises in certain contexts.[54]

B. THE REGULATORY FLEXIBILITY ACT

In another effort to recognize and correct for excessive regulatory burdens placed on smaller innovator-entrepreneurs, Congress passed the Regulatory Flexibility Act ("RFA") in 1980.[55] The purpose of RFA was to impose an affirmative duty upon agencies to actively consider the needs of smaller entrepreneurs when adopting new rules. The Act required agencies that adopted new rules to include statements detailing the impact of the rule upon smaller entities and the agency's consideration of practical means to reduce the adverse impacts.[56]

---

[53] The selection of cases to be pursued under such a "triage" system may be left to agency discretion. *See* Heckler v. Chaney, 470 U.S. 821, 831 (1985).

[54] *See supra* text accompanying notes 49-51.

[55] *See* 5 U.S.C. § 601-612 (1994).

[56] *Id.* §603(b)(4)-(5), (c) (1994). The statute states that agencies must provide:

> [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; an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule; . . . 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.

Id.

RFA's potential for effectiveness is limited, in that it does not apply retroactively to rules adopted prior to 1980. With no statutory requirement to look back at existing regulations, older rules remain in place without substantial incentives for administrative scrutiny. Furthermore, the Act's "extremely qualified and ambiguous provision for judicial review" hinders enforcement of the few prospective requirements imposed by RFA.[57] And even when agencies do follow the letter of the new law, arguably little is achieved. An agency satisfies RFA's minimal requirements when it verifies its compliance with the additional paperwork specified under the Act. Agencies can simply announce that their staffs have completed perfunctory analyses of a rule's effect on smaller entities and found no disparate impacts.[58] The statute does not include a command to actually loosen requirements affecting smaller businesses when rules are adopted,[59] nor does it provide a judicial remedy for those adversely affected by a new rule promulgated without sufficient flexibility analysis.[60]

Thus, RFA's attempt to ensure greater flexibility in the administrative regulatory framework failed utterly to achieve its purpose. This inadequacy led smaller business organizations to lobby for enactment of the Small Business Regulatory Enforcement Fairness Act ("SBREFA")[61], which amended RFA and required more detailed attention to the impact of agency rules upon smaller entities.

C. EFFECTS OF SBREFA

The adoption of SBREFA in 1996 created several potentially significant opportunities for the innovator-entrepreneur who must interact with federal regulators. SBREFA encouraged federal agencies "to answer inquiries by small entities,"[62] and directed federal agencies to assemble and disseminate regulatory guidance. Specifically, the legislation re-

---

57 *See* Paul Verkuil, *A Critical Guide to the Regulatory Flexibility Act*, 1982 DUKE L.J. 213, 259 (1982).

58 *See* 5 U.S.C. § 605 (1994).

59 *See id.* § 603 (the statute does not require modification to accommodate small business objections).

60 *See id.*, § 605 (Supp. V 1999) (allowing agency heads to determine when flexibility analysis is unnecessary).

61 *See* Small Business Regulatory Enforcement Fairness Act of 1996 (SBRFA), Pub. L. No. 104-121, tit. II, 110 Stat. 857 (1996).

62 *Id.* § 213(a), 110 Stat. at 859. SBREFA requires agencies to establish programs for responding to small entities' questions "utilizing existing functions and personnel of the agency to the extent practicable." *Id.* § 213(b), 110 Stat. at 859. In a period of budget concern for many agencies, this clause apparently represented a compromise intended to prevent agencies from delaying their implementation of the Act's requirements pending a supplemental appropriation of funds for the new function. Unfortunately, there is no definitive Senate or House Report to illuminate the full legislative intent. *See* Pub. L. No. 104-121, 1996 U.S.C.C.A.N. (110 Stat. 847) 606. A useful comment is found in Keith N. Cole, *The Small*

quires agencies to create a simplified explanatory compliance guide whenever the analysis requirement of the Regulatory Flexibility Act is triggered for a rule or group of related rules.[63] To ensure enforcement of these provisions, advisory councils of the Small Business Administration were established.[64] In addition, the Electronic Freedom of Information Act ("EFOIA") Amendments of 1996[65] empower federal agencies to disseminate their guidance documents and manuals via the Internet,[66] thereby further increasing the chances that agency guidance will ultimately reach smaller innovator-entrepreneurs.

Significantly, SBREFA also contains a provision estopping an agency from reneging on the advice provided to innovator-entrepreneurs, and/or from prosecuting or penalizing the small entity that requests the advice.[67] Though no Senate or House reports accompanied the fast-track legislation, the Republican Congress appears to have arm-wrestled the Clinton Administration to arrive at politically acceptable terms for the estoppel provision; the statute provides that guidance given to a small entity by an agency "may be considered as evidence of the reasonableness or appropriateness of any proposed fines, penalties or damages sought against that small entity."[68] This compromised wording signals Congressional refusal to give absolute immunity to small businesses relying upon agency advice.

However, even in instances where estoppel does not apply, SBREFA requires federal agencies to establish policies providing for the partial waiver of normally applicable civil penalties "for violations of a statutory or regulatory requirement by a small entity"[69] under certain mitigating conditions, including a showing of a good faith effort to correct the problem and, possibly, voluntary participation in a compliance assistance or audit program.[70] Agencies may not apply the reductions to "serious health, safety or environmental threats," nor to small entities that "have been subject to multiple enforcement actions by the agency."[71] For those who qualify, SBREFA presents a viable opportu-

---

Business Regulatory Enforcement Fairness Act and the Regulatory Flexibility Act: Could a Single Word Doom the New NAAQS?, 11 TUL. ENVTL. L.J. 281, 289-90 (1998).

63 SBREFA § 212(a), 110 Stat. at, 858.

64 § 222, 110 Stat. at 861.

65 *See* Electronic Freedom of Information Act Amendments of 1996, Pub.L. No. 104-231, §552(a)(2), 110 Stat. 3048, 3049 (1996).

66 *See* Memorandum for Heads of Departments and Agencies, *available at* http://www.usdoj.gov/ag/readingroom/99093.htm (September 3, 1999) (in which the Attorney General urges all agencies to disclose as much information as possible via electronic means).

67 *See* SBREFA §213(a), 110 Stat. at 859.

68 §213(a), 110 Stat. at 859.

69 § 223(a), 110 Stat. at 862.

70 § 223(b)(1-6), 110 Stat. at 862.

71 § 223(b)(1-6), 110 Stat. at 862.

nity to avoid potentially bankrupting civil penalties for regulatory noncompliance. And there is some evidence that agencies have implemented and publicized these statutorily required waiver policies. The EPA, for example, has told Congress that it is "aggressively marketing" its reduction program to smaller business.[72]

Finally, SBREFA helped to ensure greater accountability and adherence to its statutory mandates by modifying RFA to include judicial review provisions. In this manner, SBREFA attempted to cure agencies' prior reluctance to engage in the good faith flexibility analysis required under RFA.[73] SBREFA permits judicial review when an agency fails to perform an adequate analysis of the effects of a proposed rule on small business. However, the remedies are limited and do not include outright rejection of the proposed rule. Rather, the court may remand the rule to the agency for analysis and/or may enter an order "deferring the enforcement of the rule against small entities unless the court finds that continued enforcement of the rule is in the public interest."[74] Thus, under SBREFA, agencies are deterred from ignoring the small business analysis requirements because, if they do so, their proposed rules might be unenforceable against smaller businesses until the agency performs the analysis.

The combination of the compliance guide and facilitated Internet access to policy manuals, guidance documents, and interpretations could be very helpful for the smaller innovator-entrepreneur. Each source makes the regulatory regime more transparent to those charged with compliance—though none of these devices simplify the content or lessen the potential impact of federal regulation upon the innovator -entrepreneur. However, while information may now be flowing more freely from agencies than it once was, federal regulators could do more to address the informational needs of entrepreneurial innovators.

III. RESPONSIVENESS MODELS FOR THE TWENTY-FIRST CENTURY – CREATING THE DUTY TO ASSIST

A futuristic model of regulatory agency interaction with innovative, entrepreneurial businesses includes several additional vehicles for communication. Some agencies already utilize websites to interact with constituents, accept submissions of comments on proposed rules via e-mail,

---

72 EPA Rep. to Congress, The Small Business Regulatory Enforcement Fairness Act Section 223 Penalty Reduction Program for Small Entities, at § 4.0, *available at* http://www.usdoj.gov/ag/readingroom/990903.htm (March 1998).

73 *See* Cole, *supra* note 62, at 284-87 (discussing business and Congressional disappointment with EPA's failure to conduct regulatory flexibility analysis).

74 SBREFA § 242, 110 Stat. at 865.

and offer compliance guides for regulated persons.[75] More agencies will do so in the future and, by the end of the decade, there may also be broad agency acceptance of these and other measures including:

- •User-friendly agency websites
- •Compliance guides for parties seeking to educate themselves about how to comply with regulatory commands[76]
- •Interactive web-based questions and answers on regulatory topics
- •Downloadable self-audit guides
- •Forms and instructions capable of being submitted online
- •"Artificial intelligence" tutorial programs that facilitate responses to specific types of questions, using "if A then B" logic tree approaches.
- •Paperless "virtual inspection" of files maintained in a standardized electronic format that might be prescribed by agency rules
- •Use of email and videoconferencing for pre-penalty discovery and "virtual subpoenas" as tools for enforcement
- •Continuous feedback opportunities for rulemaking suggestions and concerns in place of paper comments

Cumulatively, these electronic media would help regulated persons to train themselves about compliance, and the feedback obtained from dialogue might help Washington-based regulators appreciate the complexity of the distant business climates in which regulatory burdens actually impact affected persons.

The next logical step would be statutory enactment of a basis upon which the education and interaction can take place. The specific format most likely to help small business would be the creation of a duty upon agencies to affirmatively assist smaller entities, coupled with legislative permission for the entities to rely upon the guidance that these agencies provide.

To be clear, educational interaction would not change the public law character of federal rulemaking. No one expects that the Internet will transform regulatory decision making into a totally open mass dialogue like the classic New England Town meeting.[77] Rulemaking will con-

---

[75] Agencies frequently update their websites and add improved search engines and logic designs. *See e.g.*, http://www.fda/gov (last modified Feb. 20, 2001); http://www.epa.gov (last modified Feb. 2001), etc.

[76] *See* Eugene Staley & Richard Morse, *Developing Entrepreneurship: Elements for a Program*, *in* ENTREPRENEURSHIP AND ECONOMIC DEVELOPMENT 357, 369 (Peter Kilby ed. 1971) (indicated that self-education tools are "invaluable to the small manufacturer").

[77] Boston's famous Supreme Court Justice Oliver Wendell Holmes once opined:

tinue to be a public comment and response process for the entirety of the constituencies affected. The proposed changes would involve tailoring and clarifying, not altering, current regulatory requirements.

Despite the corrective measures imposed by SBREFA, RFA has not proven effective in facilitating the innovator-entrepreneur's compliance with newly promulgated administrative rules. While SBREFA does afford small businesses an avenue for judicial review,[78] there has not been much occasion for litigation because many agencies no longer issue substantive regulations with any frequency, in light of the increased burdens of administrative analyses of new rules.[79] The fact is that the great majority of a mature agency's work involves the continuing refinement of policy through enforcement decisions and policy pronouncements, rather than through promulgation of new rules. Therefore, RFA's pre-rulemaking flexibility analysis is simply not enough to create a climate more responsive to the limited resources of innovator-entrepreneurs.

A far better structural solution would be a requirement that federal regulatory agencies actively converse with smaller entities about new and existing regulations. Congress should impose a legal duty on federal agencies to offer specific regulatory advice, binding upon the agency that will help the smaller businessperson to comply. This could be accomplished through an amendment to RFA, or by amending the Administrative Procedure Act notice process.[80] Congress took a small step in this direction with the SBREFA guidelines, but much more could and should be done.

The closest existing analogy to this proposed agency duty to assist may be the Department of Veterans Affairs' ("DVA") statutory duty to assist a veteran who applies for benefits. The DVA must help the veteran seeking benefits in gathering evidence and provide counseling about benefit criteria.[81] If the DVA denies a claim on the merits but substan-

---

> The Constitution does not require all public acts to be done in town meeting or an assembly of the whole . . . (the people's) rights are protected in the only way that they can be in a complex society, by their power, immediate or remote, over those who make the rule.

Bi-Metallic Investment Co. v. State Bd. of Equalization, 239 U.S. 441, 445 (1915).

[78] *See supra* text accompanying note 74.

[79] Critics have observed that rulemaking has become "ossified" because of the growth of such analysis requirements. *See generally* Richard J. Pierce, Jr., *Seven Ways to Deossify Agency Rulemaking*, 47 ADMIN. L. REV. 59 (1995).

[80] *See* 5 U.S.C. § 555(e) (1994) (requires agencies to explain the reasons for denial of applications or petitions).

[81] 38 U.S.C. § 5107(a) (1994). Traditionally, no attorneys were available to veterans so Congress imposed special obligations of assistance upon the agency. *See* Walters v. Nat'l Ass'n. of Radiation Survivors, 473 U.S. 305, 310 (1985), *rev'd sub nom.* Nat'l Ass'n of Radiation Survivors v. Derwinski, 1992 U.S. App. LEXIS 30792 (9th Cir. 1992) ("The board is required by regulation 'to assist a claimant in developing the facts pertinent to his claim,' . . . and to consider any evidence offered by the claimant.").

tially fails to meet its duty to assist, then the claim is not deemed final and the veteran can appeal further.[82] A less potent duty to assist arises in social security disability hearings in which an administrative law judge has an affirmative duty to develop the evidence in the adjudicative proceeding.[83] Creation of a similar type of duty to assist the smaller innovator-entrepreneur would significantly aid smaller business entrepreneurs in understanding complex regulatory goals, standards, and norms, and enable higher rates of compliance among those who want to comply with agency regulations, but who need guidance in understanding the specifics of a rule or requirement.

In addition, if smaller innovator-entrepreneurs could rely on inexpensively obtained agency advice, they would be better equipped to compete with larger businesses. As discussed earlier, many federal agency expectations are not transparent, and larger entities within the regulated community have an advantage over their less wealthy competitors, in that they can afford to hire well-connected Washington insiders to interpret the agency intent behind a given rule. This imbalance cannot be rectified by equalizing the disparities in affluence among regulated firms, but the government *can* take steps to level the informational playing field by providing reliable agency advice through the media of communication that are most accessible to under-privileged innovator-entrepreneurs.

Requiring federal agencies to assist smaller entrepreneurs in their regulatory compliance will help the innovator to deal with or avoid each of the three basic categories of federal agency action: (1) rulemaking; (2) adjudication; and (3) judicial enforcement. A statutory duty to assist would enable greater participation in the entire process; with greater familiarity, the smaller innovative entity could be induced to supply its unique perspective to the decision makers and could be expected to have fewer court cases or penalty adjudications.

A. DEFINING THE SCOPE OF THE DUTY TO ASSIST MODEL

1. *Qualified or Conditional Responses*

This proposal of a statutory duty to assist is premised upon the assumption that agencies will dispense accurate and helpful advice upon request. However, one must recognize the nature of the source: agency advice will, of course, consist of self-serving interpretations of statutes, rules, and other norms. The business entity may inquire as to what rule

---

[82] Hayre v. West, 188 F.3d 1327, 1334 (Fed. Cir. 1999).

[83] *See* 42 U.S.C. § 405(d)(g); Bluvband v. Heckler, 730 F.2d 886, 895 (2d Cir 1984) (holding that an administrative law judge failed in his duty to explore claimant's documented history of emergency treatment); Williams v. Mathews, 427 F.Supp. 63, 66 (S.D.N.Y. 1976) (holding that the judge should have used its subpoena power under 42 U.S.C. § 405(d) to obtain additional records from applicant's physician).

applies, what the rule means, or what it means for an entity in its particular circumstances. While requiring the agency to give accurate and timely answers to these questions will, no doubt, assist the entrepreneur greatly, it is equally beyond doubt that agencies will include qualifiers and limitations in their advisory opinions. Agencies are aware of the weight that later observers could place on their advice, so the inherent conservatism of the bureaucrat may lead to the use of qualifiers and hedge words such as "the application is approvable for use of this drug on minor cuts without extensive clinical studies; but of course the general requirement for such studies will apply if this or any other drug were to be used for major skin abrasions or wounds."

2. *Enforcement Thresholds*

Furthermore, even in the face of a statutory duty to assist smaller entrepreneurs, federal agencies are not likely to disclose or predict the level of non-compliance they are willing to tolerate without initiating an enforcement action. Revealing such thresholds for enforcement would be counterintuitive, for it would encourage entities to set their compliance at a level just shy of the point that would trigger an agency response.[84] Agencies generally only publish their thresholds for action when total compliance is acknowledged to be impossible. For example, the FDA adopted regulations delimiting quantitative tolerances for unavoidable contaminants in foods such as dirt residues left on potatoes.[85]

More sophisticated and financially prosperous firms engage private attorneys and regulatory experts, often former agency personnel, to provide invaluable advice as to what minimum level of compliance will be tolerated by a given agency. This is an advantage that larger, more established companies will inevitably continue to retain over their smaller entrepreneurial competitors, even with the implementation of a statutory duty to assist. For example, a statutory duty to assist a small food importer would require the Customs Service to answer questions about customs regulations in a timely and reliable manner, but Customs officials will not divulge the extent to which the entrepreneur might fail to comply with those regulations without risking an enforcement action. The larger entity, however, will still be able to secure the services of a former Customs employee as an expediter or private consultant who can then advise the company whether and to what extent the Customs Service will overlook non-compliance in a given area. This type of leverage simply can-

---

[84] Most agencies deny disclosure of their thresholds for enforcement when requested under the Freedom of Information Act. *See* 5 U.S.C. § 552(b)(7)(E) (1994) (authorizing agencies to deny disclosure of information regarding investigative techniques and procedures of enforcement where doing so "could reasonably be expected to risk circumvention of the law").

[85] *See* 21 C.F.R. § 109.3-109.4 (1999).

not be eliminated as long as the advice and experience of former agency personnel and insiders continues to be available to the highest bidder. It would clearly be inappropriate to permit, much less require, current agency personnel to inform smaller entrepreneurs of the agency's specific enforcement thresholds.

3. *Self-Reporting and Immunities*

The duty to assist model also cannot apply to self-reporting duties that agencies demand from all licensees and regulated companies.[86] Where the innovator-entrepreneur is required to self-report a problem with its product, then requiring the agency to provide additional information about product compliance becomes superfluous in certain situations (i.e., someone who inquires whether to report a problem that they in fact have an obligation to report will, of course, be told to report it.)

However, Congress must carefully consider what consequences should most appropriately attach when an entity initiates an agency inquiry during which it inadvertently admits a self-reporting or other violation. In keeping with a current statutory trend at the state level, federal duty to assist legislation should mandate an agency presumption in favor of mitigating penalties by a large percentage where company disclosures of violations are actual or voluntary, and not made during an audit or inspection.[87] Some feel that reduced penalties or grants of qualified immunity in exchange for voluntary disclosure of violations encourage future self-correction of non-compliance, and avoid penalizing the unsuspecting offender who wants to comply but whose failure to do so stems from an honest lack of familiarity with the regulations. However, several key federal agencies, including the EPA, vigorously oppose the use of qualified immunity from penalties, regarding the practice as a dangerous reduction in an agency's ability to enforce its authority.[88]

---

[86] *See* 15 U.S.C. § 2064(b) (1994) (consumer products); *see also* 21 U.S.C. 360i(a) (Supp. IV 1998) (medical devices).

[87] *See e.g.*, OHIO REV. CODE ANN. § 3745.72 (1999) (self-reported discovery of environmental violations immune from liability if qualifying conditions are met). State statutes have evolved from defense of audit contents to a defense of self-reports. ELIZABETH GLASS GELTMAN, A COMPLETE GUIDE TO ENVIRONMENTAL AUDITS 212-214 (1997); James T. O'Reilly, *Environmental Audit Privileges: The Need for Legislative Recognition*, 19 SETON HALL LEGIS. J. 119, 148-50 (1994) (discussing the EPA's successful defeat of a company's attempts to claim self-audit immunity); Gerson H. Smoger, *New Environmental Laws Muzzle Critics*, TRIAL, Oct. 1997, at 71-73 (discussing state statutory immunity against environmental violations for companies that conduct self-audits).

[88] *See generally* James Meason, *Environmental Audits, Privileges from Disclosure, and Small Business Penalty Policies*, 18 N. ILL. U. L. REV. 497, 507 (1998).

B. ESTOPPEL ELEMENT OF THE DUTY TO ASSIST

1. *Why an estoppel provision is needed*

A statutory duty to assist would be largely ineffective for innovator-entrepreneurs without a concomitant legal right to rely upon the assistance provided. Under the present system, administrative agencies may successfully disclaim accountability for the advice they dispense, even where a regulated individual detrimentally relies on the advice.[89] Agencies rarely empower their staff to give binding effect to an advisory opinion[90] nor are they compelled to do so. More commonly, perhaps in response to the increasingly burdensome rulemaking procedures mandated by Congress,[91] administrative agencies announce policy changes through the adjudication process,[92] and are rarely estopped from doing so.[93] Therefore, a statutory duty to assist innovator-entrepreneurs must incorporate some form of limited estoppel to bind agency official's written responses. For example, Congress could require that the agency designate a set of officials to sign the binding opinion letters.[94] At the same time, in deference to the fact that many agency responses necessarily involve nuances of administrative policy not easily conveyed, the agency must be permitted to prominently display on its website a disclaimer of binding authority for other less authoritative manuals or policies, as well as an indication of how the inquiring person can obtain a timely and binding reply to other questions. Current models for binding opinions

---

89 Fed. Crop Ins. Co. v. Merrill, 332 U.S. 380, 383 (1947) (the classic case of reliance followed by disavowal).

90 *See* 21 C.F.R. § 10.85(g), (h) (2000).

91 *See supra* text accompanying note 56.

92 *See* NLRB v. Bell Aerospace Co., 416 U.S. 267, 272 (1974). *But cf.* Puerto Rico Aqueduct & Sewer Auth. v. EPA, 35 F.3d 600, 607 (1st Cir. 1994) *cert.* denied, 1995 U.S. LEXIS 1024. The case states that although

> it is well established that agencies are free to announce and develop rules in an adjudicatory setting . . . of course, there are limits on this freedom. As a general matter, when an adjudicating agency retroactively applies a new legal standard that significantly alters the rules of the game, the agency is obliged to give litigants proper notice and a meaningful opportunity to adjust.

Id.; *see also* SEC v. Chenery, 332 U.S. 194, 201-02 (1947).

93 *See* Schweiker v. Hanson, 450 U.S. 785, 788 (1981); Akbarin v. INS, 669 F.2d 839, 842 (1st Cir. 1982). The *Akbarin* states:

> The traditional doctrine of equitable estoppel does not apply fully in cases of estoppel against the Government. For the Government to be estopped, it is necessary not only that a party have relied on the Government's conduct - the basis of the traditional doctrine - but also that the Government have engaged in "affirmative misconduct" . . . even when affirmative misconduct and reasonable reliance occur, however, it is not clear that the Government should be estopped.

Id.; *see also* U.S. v. Ruby Co., 588 F.2d 697, 704 (7th Cir. 1978) (indicating that government action should only be estopped where there are "compelling reasons to do so").

94 This could be, for example, the chief enforcer or chief lawyer of the agency.

include antitrust opinions issued by the U.S. Department of Justice.[95] Even non-binding agency pronouncements may have utility to some regulated firms but in order to obtain optimal benefit for the entrepreneur; there must be a form of administrative agency estoppel that prevents a reversal of position after responses to specific inquiries are given.

2. *Limiting use of estoppel to smaller innovator-entrepreneurs only*

Of course the limits of the estoppel feature must be defined clearly and restrictively so as to eliminate any potential for abuse. A duty to assist statute must categorize those entitled to the duty to assist, so that binding agency guidance would only become available to smaller innovator-entrepreneurs. Without this restriction, larger firms would be able to take advantage of the service's estoppel benefit and delay an agency's ability to respond to genuine requests by clogging the system with sham inquiries. Limiting access to agency information for some parties while making it available to others is not unprecedented.[96] Nor is restricting estoppel to smaller concerns unfair in this instance, since larger entities normally rely upon consultants or intermediaries to meet their regulatory advisory needs, and thus do not require the protection offered by the duty to assist estoppel provisions. The statute should not provide yet another advantage to larger firms that can already afford to pay for expert advice by granting them a binding confirmation of the accuracy of that advice as well. In keeping with its aim of equalizing information flow, the duty to assist statute should properly benefit only those who presently cannot afford independent and reliable regulatory compliance advice.

3. *Limiting even the innovator-entrepreneur's use of estoppel*

Neither should the smaller entrepreneur be able to abuse the advantages of the estoppel provision. When using the duty to assist system, the questioner must act prudently and provide all information the agency might require to render accurate advice. Fraudulent concealment of predicate facts should void the binding effect of the agency's advice, since agency response must be conditioned upon assessment of the facts as presented by the inquirer. Likewise, should the agency become aware that the facts underpinning its prior advice no longer apply, the agency must be able to provide notice that it will no longer be bound by that past advice. Prudent agencies might incorporate into their advice letters both

---

[95] *See* 28 C.F.R. § 50.6 (1999).

[96] For example, pesticide data cannot be examined by employees or agents of multinational companies. 7 U.S.C. § 136h(g) (1994). In addition, the Freedom of Information Act requires persons seeking free services to identify their role as scholars or journalists as a prerequisite to fee waiver. 5 U.S.C. § 552(a)(4)(A)(ii)(II) (1994).

the material facts of the inquiry and a standard clause of disengagement, so that the small entity will be placed on notice of the agency's understanding of the basis for the advice and the possibility of its retraction in the event of changed circumstances. Such actual notice of the agency's policy provided to a specific regulated entity should foreclose that entity from later arguing that the advice is invalid due to the agency's failure to publish or index its policy as required under the Freedom of Information Act.[97] However, those who fail to comply with the advice provided by the agency should be subject to normal enforcement procedures, as would any other non-compliant party, because any perception that agencies might target for investigation those who seek help would likely dissuade entrepreneurs from using the duty to assist program.

4. *Limiting the estoppel period*

The statutory estoppel clause should also be limited as to time and effect so that smaller entities can legally rely on a given agency opinion for no longer than eighteen months. Since administrative policies must, by their nature, evolve over time and adapt to changing circumstances and issues, it would be improper to bind an agency permanently to advice provided under the program. Providing a prospective expiration date for the duty to assist advice within the body of the legislation itself will prove more predictable for the users and simpler for the agencies to manage than an ad hoc system of withdrawing advice if and when it becomes necessary for the agency to do so. All advice provided under the duty to assist regime could be archived and electronically flagged to indicate when a letter has passed its statutory estoppel period. Of course, even expired advice might still be a sound reflection of a continuing agency policy. However, the smaller entity seeking to extend its legal reliance upon that advice would have to submit another request for the same opinion, or perhaps request a re-certification of the advice in order to protect its estoppel rights.

In addition, entrepreneurs must be permitted to invoke the estoppel defense only during agency enforcement proceedings. Even reliance upon a valid agency opinion should not justify an estoppel defense in a *criminal* proceeding. Federal prosecutors are reluctant to exempt individuals from criminal prosecution simply because they may have legitimately acted with what they thought to be the informal authority of a government agency. For example, a mail fraud prosecution under federal criminal law[98] could proceed against a food marketer whose claims induce Internet purchasing of health foods, even if the company's claims

---

97 *See* 5 U.S.C. § 552(a)(2).

98 *See* 18 U.S.C. § 1341 (1994).

complied with the Federal Trade Commission's ("FTC") standards,[99] because the Department of Justice and the FTC have separate channels for identical conduct. Given this societal distaste for excusing criminal behavior, any estoppel provision attaching to the duty to assist must be limited to enforcement proceedings at the agency level. However, the criminal standard of requiring proof "beyond a reasonable doubt" should mitigate any unfairness toward the criminal defendant who innocently relies upon agency advice.

IV. ALTERNATIVES TO THE DUTY TO ASSIST

A. THE INTERNET MODEL

The abundance of regulatory information now available through the Internet is enormous and encouraging. Certainly, to the extent that the problem is lack of information, the cure is more access. However, efficient delivery of information is useless if those who receive it are incapable of processing it appropriately. The innovative entrepreneurial firm needs more than mere access to regulatory requirements; it needs guidance and direction on which requirements are applicable to it and which are not, which requirements are triggered by which circumstances, etc. Entrepreneurs with innovative ideas vary widely in education, sophistication, and available time to spend on understanding nuances of the regulatory issue(s) confronting them. The Internet cannot process and correct for these differences. This can only be accomplished through an interactive dialogue rather than a "data dump."

A duty to assist approach combines all of the advantages of the Internet's informational capabilities while eliminating its disadvantages. An entity entitled to receive assistance could be coached by an intelligent interactive website to find the particular documentary resources, forms, or advice it required. When information failed to surface via the website, users could send email requests for targeted answers to fact-specific questions, which could in turn be processed by an actual correspondent within the agency.

B. OMBUDSMAN MODEL

Traditionally, ombudsmen have served as complaint investigators assisting aggrieved citizens in reaching amicable settlement of disputes.[100] At least one agency[101] has adapted this concept to create an

---

[99] Federal Trade Commission, Enforcement Policy Statement on Food Advertising *available at* http://www.ftc.gov/bcp/guides/guides/htm (May, 1994).

[100] WEBSTER'S NEW WORLD DICTIONARY (Victoria Neufeldt ed., 3d college ed. 1988.)

[101] Other agencies with small ombudsman offices include the CPSC. *See* Consumer Products Safety Commission, Small Business Ombudsman, *available at* http://www.cpsc/gov/businfo/ombud.html (last updated Feb. 21, 2001).

"interactive ombudsman" who serves as a regulatory coach of sorts, offering affirmative training for successful compliance with agency regulations and standards. The EPA's website explains the mixed roles of its Small Business Ombudsmen program in depth.[102] The EPA staffs its office with engineers and economists, and much of their work focuses on particular problem calls with some attention paid to input concerning particular proposals. The expense of providing such tailored services may be prohibitive for some agencies and non-problematic for others; on balance, this article's alternative suggestion for reaching more constituents through Internet information services would be a more efficient choice.

C. ARTIFICIAL INTELLIGENCE MODEL

Another model involves the use of an "e-mail advisor," an artificial intelligence program, resident inside the agency's website. Artificial intelligence refers to a software program that processes pre-loaded sets of decisional factors and provides pre-programmed responses according to the inputs selected by the user. An agency could provide this service on its website. Where the programmed questions and responses failed to yield the information the user seeks, an agency staff person would then respond to the question via email in a form that shielded the particular inquirer's identity. Confidentiality would be of particular concern with inquiries made to such agencies as the Internal Revenue Service and Securities and Exchange Commission, since serious economic and/or criminal liability could attach to the inquiring party. For this reason, any statute designed to implement such an "email advisor" plan should include an exemption to the normal requirements of public accessibility of agency records under the Freedom of Information Act.[103]

D. DIMINISHED COMPLEXITY OF COMPLIANCE STANDARDS

Alternatively, federal agencies could experiment with new, less complex, regulatory methods and procedures that facilitate compliance by the unsophisticated innovator-entrepreneur. Some agencies are already exploring this concept. For example, the Securities & Exchange Commission ("SEC") has begun to permit Internet solicitation of investors in smaller enterprises.[104] Under the SEC's program, investors in

---

[102] EPA, EPA Small Business Ombudsman's (SBO) Homepage, *at* http://www.epa.gov/sbo (last modified Jan. 29, 2001).

[103] *See* 5 U.S.C. § 552(a) (1994) (Supp. V 1999) (describing normal accessibility requirements); *see, e.g., id.* § 552(b)(3)(B) (1994) (providing for exemptions to public access requirements when mandated by other statutes).

[104] *See* Daniel Giddings, *An Innovative Link Between the Internet, the Capital Markets, and the SEC: How the Internet Direct Public Offering Helps Small Companies Looking to Raise Capital*, 25 PEPPERDINE L. REV. 785, 789 (1998).

smaller enterprises can be given required information with less paperwork. In another program, dry cleaners and other smaller generators of hazardous waste can claim exemptions from EPA rules governing the handling of larger quantities of hazardous wastes.[105] But sometimes agencies override objections of smaller firms and demand uniform compliance without exception.[106]

V. ANTICIPATED CRITICISM OF A DUTY TO ASSIST

A. COSTS

A statutory duty to assist will require increases in federal agency funding, personnel, equipment and staff workload. Such a progressive and expensive program is not assured the support of the small business innovator-entrepreneurs it is designed to help, because both small business entrepreneurs and larger firms generally dislike bureaucracy, "big government," and high taxes.[107] No doubt some entrepreneurs and some congressional appropriators will agree when the larger firms paint the duty to assist model as a wasteful addition to the taxpayers' already considerable burden.

The agencies themselves may also resist the idea of a statutory duty to assist on cost grounds. To the extent that Congress may be reluctant to authorize additional appropriations to implement a duty to assist program, there may be internal agency staff opposition to reallocating enforcement funding toward support of advice programs. However, at the same time, once smaller entities begin to use agency advice as a basis for estoppel in enforcement proceedings, the agencies will likely require more funding to maintain effectiveness in their enforcement divisions. Without this additional funding, agencies may be encouraged to devise rules that restrict the efficacy of the duty to assist program in an enforcement proceeding.[108] Agencies might also attempt to pass on the higher costs to the regulated community. Experience with the EPA's hazardous waste program suggests that penalties increase as rules rigidify, because

---

105 40 C.F.R. §261.5 (2000). Congress specifically required EPA to examine the feasibility of such an exemption in the 1984 amendments to the Resource Conservation & Recovery Act. *See* 42 U.S.C. §§ 6901-92 (1994); H.R. REP. No. 98-198, at 103, *reprinted in* 1984 U.S.C.A.A.N. 5636, 5674.

106 *See e.g.*, Food Labeling: Warning and Notice Statement; Labeling of Juice Products, 63 Fed. Reg. 37030, 37053 (July 8, 1998) (overriding the objections of farmers with roadside apple juice stands to processing and labeling requirements).

107 Kathleen Bawn, *Political Decisions About Bureaucratic Accountability: Interests, Institutions, and Prospects for Reform, in* 7 ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION, AND ECONOMIC GROWTH *supra* note 48, at 37, 37 ("Nobody likes bureaucracy.").

108 For example, although DVA has a duty to assist the veteran in preparing a claim for benefits under 38 U.S.C. § 5107(a), in 1999, the agency promulgated a rule that prevents judicial reversal of a DVA action for breach of this duty to assist. *See* 38 C.F.R. 20.1403(d)(2) (2000).

the procedural formalities of the rulemaking process lessen the flexibility of the enforcement program.[109] Perhaps a lessening of the flexibility in the advice-giving function will have a similar effect.

Although all good ideas carry initial implementation costs, those initial outlays pay dividends later. For example, the Freedom of Information Act ("FOIA") amendments of 1974,[110] which added a time-sensitive response requirement to requests for information under the Act, carried a large startup cost, and were criticized as a drain on other agency programs.[111] Yet FOIA has provided considerable benefits to society in terms of holding the federal government accountable for its actions. Likewise, the cost of a qualitatively expanded agency communication effort such as a duty to assist is directly related to its value in increasing compliance with agency regulations. Administrative regulations exist to reduce social costs of pollution, injuries, illness, etc. Increased compliance with the agencies' expected norms of performance will reduce the negative effects of noncompliance on the community. Another benefit of the duty to assist model is the opportunity it affords regulators to send a positive, persuasive signal to the regulated community about the agency's sincere desire to encourage compliance and decrease the business constituency's negative perception of their role. The EPA Small Business Ombudsman website, for example, is an excellent counterpoint to that agency's legendary enforcement reputation.[112] Thus, the costs of implementing worthwhile programs diminish considerably when weighed against the long-term benefits they generate.

In addition, critics should keep in mind that many of the costs associated with the duty to assist model are already incurred by administrative agencies in diverse ways; local offices and ombudsmen of federal agencies already answer small businesspersons' telephonic and written requests for information. Where the duty to assist model differs is in its creation of a statutory *duty* to provide an Internet response to the inquiring person upon which the entrepreneur can rely in managing the bureaucratic norms applicable to the enterprise.

Agency costs could be further reduced by several applications of available technology, such as downloadable tutorial training programs. Artificial intelligence software programs could be employed with tailored messages responding to frequently asked questions. Adapting this

---

109 James T. Hamilton, *Going by the (Informal) Book: The EPA's Use of Informal Rules in Enforcing Hazardous Waste Laws*, *in* 7 ADVANCES IN THE STUDY OF ENTREPRENEURSHIP, INNOVATION AND ECONOMIC GROWTH *supra* note 48, at 109, 151.

110 *See* 5 U.S.C. § 552(a) (1994).

111 The 1966 Act and the 1974 amendments met with some initial resistance within federal agencies. *See* 1 JAMES T. O'REILLY, FEDERAL INFORMATION DISCLOSURE § 2.03 (2d ed. 1990).

112 *See* EPA, *supra* note 102.

commercially available software for familiar inquiries would reduce the cost per response. Later inquirers could be guided to search keywords in the electronic database of searchable answers, reducing the number of repetitive questions on the same topic.

Finally, the agencies' costs might be reduced through additional Congressional appropriations. The agencies that make visible efforts to serve their constituencies by earnestly implementing the duty to assist model are more likely to receive additional funding for the program once Congress begins to hear from its constituents that the program is working and is helpful. Appropriations subcommittee members hear from their small business constituents frequently and make budget recommendations accordingly.

There is no question that, however justifiably, the imposition of a new statutory duty to render useful and reliable advice would impose a substantial administrative cost upon agencies. In a sense, taxpayers would be doubly burdened, paying once to support the inspection and enforcement functions of the agency and yet again for the expansive counseling role a duty to assist would force agencies to assume. Does the expenditure of such funds on a business advisory function externalize what should be internalized costs of doing business? Will the funding produce the net social benefit discussed above? Or will some innovator-entrepreneurs continue to take regulatory risks regardless of whether they have ready access to agency advice? Reasonable minds might differ over the answers to these questions and come to varying conclusions as to whether the cost of the duty to assist is justified by the types of possible benefits outlined above.

B. DOES OFFERING ADVICE MAKE ANY DIFFERENCE?

It is impossible to offer a blanket guarantee that a statutory duty to assist will improve the problematic state of relations between smaller innovator-entrepreneurs and federal administrative agencies. However, data on consumer satisfaction about the utility of such a function could be gathered both before and after the duty to assist model is initiated. If the agencies' new duty to provide advice is well publicized, yet draws minimal utilization, or if entrepreneurs who receive advice tell surveyors that it does not influence their actions, then the project may fail and be phased out.

Even if the project is successful, at least some innovator-entrepreneurs would likely continue either to take uninformed risks, or pay marketplace rates for the expert advice of consultants or attorneys, rather than rely upon agency advice. Further, assessing the success of a duty to assist initiative among those who chose to use it might be a difficult task; data demonstrating a tangible benefit would require proof of why some

potential violation did not happen, and it is hard to prove a negative regarding conduct that is subject to complex causation.

For purposes of this analysis, we assume that at least a small portion of regulated innovator-entrepreneurs would take advantage of regulatory advice provided by administrative agencies under a statutory "duty to assist." Entrepreneurs who must obtain specific product or service approval would be particularly likely to use the advice option because their interactions with the agency are inevitable. With time and experience, the advice function component of the duty to assist could be adapted within each of the various agencies to produce one or more successful models. No one assumes this will be painless for bureaucrats or entrepreneurs. Mutual distrust developed over decades will inhibit acceptance of the new models proposed herein. But the models can be made to adapt to the particular setting of the several agencies' constituencies. Congress should provide a framework of legal authority and allow the agencies to find the methods that work best in their individual contexts.

VI. CONCLUSION

Entrepreneurial innovators developing products or services today are caught in a regulatory catch-22: they can remain invisible below the federal agency's enforcement "radar" and guess at what the agency's norms might be, or they can become visible to the agency by risking an inquiry and await agency guidance in response, thus risking an enforcement challenge. A more optimal regulatory regime would involve advice, feedback, and greater dialogue such as the statutory duty to assist proposed in this article.

More effective use of the Internet would meet the smaller entrepreneur's advisory needs and possibly foster better relations with regulators through the establishment of a two-way dialogue. Congress should build upon SBREFA by appropriating funds for an Internet-based, responsive, interactive communications process to which smaller businesses can link and obtain regulatory advice from each federal agency. A pilot program in two or three agencies should demonstrate the efficacy of this method of constituency interaction.

The changes this article proposes would have significant social benefits. Well-informed compliance of smaller businesses reduces alienation and resentment of government's role in the economy. Enhanced voluntary compliance with regulations saves dollars that would otherwise have to be spent on cumbersome enforcement proceedings. And clearer regulations enable regulated companies to avoid costs of re-working projects or re-labeling products that would otherwise be passed on to consumers.

In the age of technology and information, there is no excuse for allowing regulatory complexity to go unexplained. Congress should recognize its responsibility for providing clear and reliable agency advice. The agencies should begin offering the duty to assist service, and the Congress should follow with the modification of estoppel policies through statutory reform. Together, Congress and the enlightened agencies should embrace the learning tools of the twenty-first century and employ them to promote compliance with the regulatory objectives of the federal government.