

Agency Reform*

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* March 24, 2001. Moderator: Joan Claybrook, President, Public Citizen. Panelists: David G. Hawkins, Director of Air and Energy Program, Natural Resources Defense Council and Patricia M. Sullivan Environmental Chair; Jim Hightower, former Texas Agriculture Commissioner, radio journalist, and consumer advocate; David A. Swankin, President and CEO, Citizen Advocacy Center; Sidney M. Wolfe, M.D., Director, Public Citizen Health Research Group.

I. STATEMENT OF ISSUES

The agency reform agenda is driven by an underlying lack of effective representation of broad and future interests before the executive branch. Those with short-term proprietary interests in agency policies and enforcement exercise disproportionate influence, often undermining legislative intent and failing to adequately reflect the broad interests of the body politic. Those broader interests include the concerns of the underrepresented, diffuse consumer interests, and future concerns. The areas of inquiry to be covered in this session include the following: (1) sources of bias (conflicts, job interchange, funding, ossification); (2) information and advocacy imbalance (competence, information, balance, procedural fairness); (3) public access; and (4) media attention.

After discussing each of these problem areas, the Summit will consider seriatim proposed solutions from which priorities may be distilled and strategies developed.

II. CURRENT PROBLEMS

The executive branch has grown in size, complexity, and importance over the past fifty years. That trend is likely to continue. Legislatures enact broad enabling statutes and turn the details over to agency officials. Most often, these advisory responsibilities are turned over to regulatory bodies, which coalesce executive powers with quasi-legislative (through rulemaking) and quasi-judicial (through discipline or other enforcement) authority. The devil can be in the details.

The promise of such agency regulation is immense. Agencies are intended to ameliorate market flaws, for example, where natural monopoly, scarcity, or external costs impede its proper function. Such flaws can lead to irreparable harm. Although tort litigation may assess wrongdoers in court after damage occurs, regulators can act in advance to prevent it. Further, a regulator can act across an entire profession directly rather than relying on uncertain deterrent impact from occasional tortious acts litigated to judgment. For example, the *1990 Harvard Medical Practice Study* of physician negligence in a hospital setting concluded that less than five percent of negligent decisions causing damage result in vindicating civil suits.¹ Sole reliance on civil litigation has profound limitations—either as a mechanism to assure

1. HARVARD MEDICAL PRACTICE STUDY, PATIENTS, DOCTORS, AND LAWYERS: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION IN NEW YORK (1990).

compensation or to minimize harm through accountability.

However, such theoretical regulatory efficacy has been belied by serious failures. From the savings and loan debacle to Firestone tires and many examples in between, serious abuses by regulated professionals go undetected and undeterred. In fact, the less efficient mechanism of outside private litigation has checked a great deal of harmful behavior by persons fully subject to regulatory monitoring. What can be done to make agencies more effective in their assigned task and more responsive to the general public and to future interests? We identify two problem areas for discussion: bias and ossification self-censorship.

A. Bias

Agency officials often manifest conscious or unconscious bias in favor of those with a proprietary, short-term stake in their policies. Apart from the campaign finance issue affecting those who appoint agency officials, we encounter bias emanating from direct conflicts of interest, lobbying, job interchange, and information domination.

1. Agency Officials and Conflicts of Interest

Laws exist federally and in some states requiring high agency officials to disclose personal holdings that might relate to their public decisions. What is the coverage of such laws? Do they present definitional problems? Is enforcement effective or likely? Is disclosure enough of a check? The materials accompanying this Session summarize current federal law applicable to conflicts and disclosures required of agency officials. The laws of many states go well beyond federal law in requiring the disclosure of holdings and income, but still have some common loopholes.² How should federal and state law be strengthened?

Beyond personal conflicts, what can be done about the bias flowing from campaign contributions to the appointing authority (gifts likely known about by the agency officials)? This Session's materials include documents indicating the severity of this source of financial bias in the current federal administration.³

Another set of laws common among the states requires an official

2. See, e.g., CAL. GOV'T CODE §§ 81000–91000 (West 1993 & Supp. 2003).

3. See Press Release, Democracy 21, President Bush's Fortune Seeking 100 Invest \$35 Million in White House Portfolio (March 8, 2001), at <http://www.democracy21.org/index> (last visited Feb. 1, 2003).

making a decision or casting a vote in which he or she has a personal financial stake to refrain from acting officially to further that private interest. Included in the Session's materials is a typical state provision governing recusal requirements where there is such an individual conflict.⁴

Beyond personal income and assets of executive branch officials, many agency officials are appointed directly from the trade or industry regulated by the agency. In fact, where boards or commissions run executive agencies (as is often the case with state regulatory bodies), officials are often required to be from an affected trade or industry. These persons may recuse themselves from an issue that impacts their own personal business, but does their tie to the regulated industry raise underlying issues of fairness and impartiality? If the state regulates on behalf of the broad body politic in order to restrain abuses by profit-stake interests, should those interests then dominate the public agency acting for the general public?

Consumer advocates have long argued that the occupational ties of officials bias them as much as (or more than) personal financial conflicts. They argue that the reorganization of our society into horizontal or peer groups of colleagues performing similar tasks creates allegiance to an occupational "tribe," which in turn subconsciously determines official agendas. Such decisionmakers can be harsh on the outcasts within their trade or industry, but the tribal rules generally tend to be accepted or assumed. Hence, state bars are governed by attorneys who rarely place on their regulatory agendas any of the following issues of some interest to the general public: excessive attorney billing, professional dishonesty in memoranda of points and authorities, abuse of discovery and other civil litigation abuses generally, access to justice by the broad population, and failure to require malpractice insurance or to impose retesting for competence in actual areas of practice. Similar observations may be drawn whenever a trade or industry regulates its own membership, from doctors to dry cleaners.

The common argument made in response is that expertise is required to render proper judgments. Can such expertise be provided without making the experts the decisionmakers? The basic dilemma of executive branch, especially regulatory, decisionmaking is this: how do we combine independence—a broad perspective—with expertise? What alternatives should we promote to achieve such an end?

2. Job Interchange

Related to the above, many agency officials work closely with those

4. CAL. GOV'T. CODE §§ 87102.8, 87103 (West 2002).

employed within the regulated industry. Agency officials are commonly offered positions by industry, which many take postpublic employment, including work as lobbyists, before the very agency they previously governed. As is the case with such offers to legislators, it is difficult to detect an offer made to, or implied for, an agency official who is still in office. And the problem of such close connection extends beyond this deferred bribe problem (considering a future employment reward while still a public official). Close personal ties between industry and regulatory officials create an atmosphere inimical to fair consideration of future impacts contrary to the profit-stake of those being regulated.

How do we assure independence so that officials will make decisions on the merits? Should we prevent such officials from employment with an industry they regulate for a period of time after they leave office (one year, two years, or longer)? Some states ban former public officials from appearing before the agency that previously employed them for one year after employment ends.⁵ Is that enough? Should conflicts and ties (such as grants and consulting fees) be examined when appointees are from academia? Is there a qualification against bias contrary to the mission of an agency outside of direct economic ties with involved profit-stake interests? How do we formulate such a qualification?

3. *Funding*

At the federal level, funding conflicts can influence regulation. The Food and Drug Administration system for financing drug approval testing is an example. More broadly, many agencies are specially funded by fees from the regulated industry. How do such funding ties bias regulation against consumers or other broad or future interests?

B. Ossification and Self-Censorship

Many agencies must act affirmatively to carry out their mandates. Inaction can serve special interests. Accordingly, an agency can reflect a bias toward short-term profit-stake interests by finding reasons not to act. Indeed, special interest lobbyists rarely urge nonenforcement of the law or the diminution of public protection. Rather, they cite other values, such as due process, commercial free speech, or privacy as a

5. See, e.g., CAL. GOV'T CODE § 87406(c) (West 1993 & Supp. 2003).

pretext to arrange agency impotence. Many sociological and bureaucratic factors can impede agency action on behalf of broad and future interests. Among these factors are the following: an atmosphere where every decision must be by consensus of those who are recognized players, peer group caution, use of perceived media criticism, the premium against offending a powerful lobby, anticipatory rejection, and the skill of lobbyists who know which buttons to push for each agency official empowered to act.

The materials handed out for this Session discuss the current cost-benefit risk analysis often used to evaluate environmental protections and the stated substantive basis for much self-induced paralysis.⁶ Other materials outline some of the problems with Senate bill 746, which creates a federal forum for ossification.⁷ Also included is the current law governing congressional review of federal agency rulemaking.⁸ Such review, which often uses flawed risk analysis, is asymmetrically imposed against market intervention and further stimulates ossification. Should this review process be changed? How?

III. PROPOSED SOLUTIONS

A. Only Public Membership; Ad Hoc Experts

As noted above, official decisionmakers at the state and local level often come from the regulated industry. They usually perform official tasks as commission or board members overseeing an agency on a part-time basis. They generally continue to work in the same private enterprise that they coextensively regulate. The courts have drawn some occasional lines in this area. In *Gibson v. Berryhill*,⁹ the U.S. Supreme Court found due process infirmity where the Alabama Board of Optometry, consisting solely of private practice optometrists, made enforcement decisions inimical to corporate optometry interests not represented on the board.¹⁰

Similar court decisions in California invalidated adjudicatory decisions against auto manufacturers by the state New Motor Vehicle Board, which was composed only of auto dealers and public members.¹¹ These

6. LINDA-JO SCHIEROW, LIBRARY OF CONGRESS, CRS ISSUE BRIEF: THE ROLE OF RISK ANALYSIS AND RISK MANAGEMENT IN ENVIRONMENTAL PROTECTION (2000).

7. PUBLIC CITIZEN, S. 746 CREATES A "REGULATORY OBSTACLE COURSE" FOR IMPORTANT PUBLIC SAFEGUARDS (1999), at <http://www.citizen.org/congress/regulations/archives/omnibus/articles.cfm?ID=1466> (last visited Feb. 1, 2003).

8. See 5 U.S.C. §§ 801, 802 (2000).

9. 411 U.S. 564 (1973).

10. *Id.* at 578-79.

11. *Am. Motor Sales Corp. v. New Motor Vehicle Bd.*, 138 Cal. Rptr. 594 (1977).

court decisions found that the presence of dealers and the absence of manufacturers on the board deprived the manufacturers of their due process right to a fair and impartial tribunal.¹² In the area of rulemaking, some courts have drawn lines where the legislature has excessively delegated authority to industry. In *Bayside Timber Co. v. San Mateo County Board of Supervisors*,¹³ California's Judge Elkington essentially invalidated the state Forest Practice Act because it required all regulations adopted by the State Board of Forestry to be approved by two-thirds of the loggers in the region where the proposed regulations would apply.¹⁴

But these decisions are exceptions to the general weight of practice, which is to rely on those with a present profit-stake in an industry to control regulation of the industry on behalf of the broader body politic. One nonlitigation solution in this area has been the introduction of public members to such boards. Public members are persons who are not part of and have no interest in the industry or trade regulated. But such public members often end up being large campaign contributors to those making appointments or the spouses of influential members of the trade or profession being regulated. Further, where such persons are in a small minority, they are often acculturated into the point of view of the majority members from the trade or profession and may be overly impressed by the vocabulary and perceived expertise of those practitioners who dominate the agency.

What other models should be considered for such agency governance? One advantage of having a multimember board as a decisionmaker is the general requirement for public meetings, public discussion, and public decisionmaking. "Sunshine laws,"¹⁵ which allow public input in meetings, do not apply where a single agency official makes a decision in the official's office. What about a model with governance by a multimember board of public members only? Should industry or other parties be allowed to advise through advisory boards the all-public-member decisionmaking board? One advantage to such a structure is that it opens up the industry's own position for broader discussion, especially since the sunshine statutes may apply to the advisory board's activities (as opposed to the

12. *Id.*

13. 97 Cal. Rptr. 431 (1971).

14. *Id.* at 439-40.

15. The Administrative Procedure Act, CAL. GOV'T CODE §§ 11340-11350 (West 1992 & Supp. 2003); The Bagley Keene Open Meeting Act, CAL. GOV'T CODE §§ 11120-11132 (West 1992 & Supp. 2003); The Public Records Act, CAL. GOV'T CODE §§ 6250-6268 (West 1995 & Supp. 2003).

secret proceedings of trade associations).

And how do we assure that such public decisionmakers have the necessary independent expertise? Should we provide an independent staff to serve such public members, thus assuring subject matter expertise? For smaller agencies, should we have lists of experts who may be hired by such public members on an ad hoc basis?

Related to the industry bias problem is the problem of financing regulatory agencies, particularly at the state level. Fees from license applications, license renewals, or similar assessments of the regulated industry are what usually finances the regulatory scheme. Although such financing allows those who benefit from regulation—consumers, in theory—to pay for that regulation through higher prices passed on to the consumer, this type of financing has a collateral impact. Legislators and others view the industry as the financial supporters of the regulatory system and will not approve budget increases unless agreed to by the industry. Might one solution be to support an assessment that is less directly related to agency budgets? How is this best accomplished?

B. Traditional Restrictions on Conflicts and Influence

Whether or not an executive official is a practicing member of an industry or trade under his or her official jurisdiction, more specific conflict of interest dangers remain. A particular decision may disproportionately benefit an official, whether or not he is in an affected trade or industry. In those situations, most jurisdictions require recusal of the official from the decision. Hence, a real estate broker may sit on a planning commission or serve as planning director, notwithstanding a general benefit accruing from the approval of more properties to be bought and sold as subdivisions. However, where a particular property or group of properties being affected by a decision is owned by or is being brokered by the official, traditional conflict standards will generally require recusal. Are such conflicts ameliorated by existing disclosure requirements and by enforcement? What should be done to strengthen standards and compliance?

C. The Oaks Model

One proposed solution, discussed briefly in some of the other Summit sessions, focuses on the official. Under the Oaks Model, enacted in three California cities in 2000, public officials essentially enter into a contract when they take local office.¹⁶ Such office (for example, a seat

16. For a copy of an Oaks initiative, see The Foundation for Taxpayer &

on a local planning commission) is accepted with the understanding that all decisions made will be on the merits and without regard to the personal financial gain of the public official. Accordingly, where such public officials distribute significant public benefits, exemptions, privileges, and so forth, they agree not to profit personally from any person or group receiving such a gain from their public decisions. Hence, a local official who votes to grant an exclusive franchise to a trash hauler or a local cable firm, tax benefits to a business, or a major zoning variance contrary to the general plan, also agrees that he or she will thereafter (for five years or while in office plus two years) not accept from such a beneficiary *any* honorarium, gift, job, or campaign contribution.

Applying such private benefit limitation to the executive branch has clear advantages over similar measures applicable to general legislators. A local planning or other official will not necessarily grant disproportionate public benefits to large populations, but rather to defined groups related to the particular area of commerce or function of that official. Hence, beneficiaries are relatively easy to identify, and limitations on future financial opportunity for the official are accordingly circumscribed.

D. Other Models

Other existing models require placement of assets in blind trust, prohibit law practice while serving in public office, or impose conflict of interest standards closer to those applicable to judges. What alternatives might accomplish the goal of neutral and unbiased decisionmaking?

IV. INFORMATION AND ADVOCACY IMBALANCE

Even where an executive branch official lacks personal financial bias or professional loyalty to the group regulated and wants to make a decision on the merits, that official must have adequate expertise to understand what is at stake and balanced information from which to decide. Currently, that is often not the case.

Consumer Rights, *Oaks Proposal*, <http://www.consumerwatchdog.org/citizen/rp/> (last visited Feb. 1, 2003).

A. Competence

An incompetent official is more easily manipulated than a competent one. Misinforming someone is more difficult where the listener or reader is intelligent, active, and caring. Most agency officials are appointed, and many achieve office for reasons unrelated to competence—often through referrals of campaign contributors, old friends, and industry groups. Is there a way to stimulate the appointment of competent independent agency officials?

B. Information Balance

State public utility commissions well illustrate the information imbalance problem. Utilities are able to deduct the costs of lobbying as a prudent cost, passed involuntarily onto the ratepayers (whose interests the utilities often oppose). Rarely are any limits imposed on utility representation before the regulator, and it is not uncommon for utility expert witnesses to include multiple Nobel laureates. How is information and advocacy balanced so that the resulting decision reflects something more than the vectored result of here-and-now profit-stake concerns?

1. The Internal Advocacy Office

Some agencies create internal offices to represent broader interests. For example, the California Public Utilities Commission has an Office of Ratepayer Advocates that is partially walled off from the agency salary and promotion system and often provides valuable representation of consumer interests. However, such an option has limitations, including the inability to sue its own agency, to prosecute an appeal of its agency's decision, and to make statements that might embarrass the agency. Nevertheless, where a unit of government is given a mission to represent a certain interest, they often follow the tradition of their profession and do so. Can the internal advocacy model work?

What about a more independent variation, where the advocacy emanates from a separate nonprofit (perhaps tax exempt) organization that is on a long-term contract, funded outside the agency, and assured attorney fee compensation whenever it prevails?

2. Intervenor Compensation

Some agencies allow intervenor compensation.¹⁷ Under this model, a

17. In California, the Public Utilities Commission, Department of Insurance, and

consumer group that (1) intervenes in a qualifying proceeding and (2) makes an advocacy contribution that is adopted by the agency, benefits consumers, and is attributed to the consumer group by the agency in its final decision is permitted to recover the cost of its representation (including attorneys' fees at market rates and expert witness costs) from the utility or insurance company at issue in the proceeding. Should this model be expanded or applied at other agencies?

3. CUB Model

In addition to or as an alternative to the above, some states facilitate citizen utility boards (CUB), which need not be limited to utility consumer representation. These private, independent entities receive funding through billing insert appeals, traditionally getting access to the billing envelopes of the regulated industry, which generally includes empty space. Small voluntary contributions by large numbers of consumers then permit an independent entity to advocate on behalf of broader and future interests without the limitations that § 501(c)(3) status or agency supervision might impose. Such entities exist in Wisconsin, Illinois, and San Diego, California. They have helped to redress the imbalance in advocacy in the few places where imbalances exist.

The so-called billing access privilege that allowed the creation of the Wisconsin and San Diego CUBs was invalidated by a plurality of the U.S. Supreme Court in the problematic decision of *Pacific Gas & Electric Co. v. Public Utilities Commission*.¹⁸ The plurality ruled that billing inserts violate the free speech rights of regulated utilities that may be forced to speak, given the possible consumer confusion over a message in their envelope from a different entity (even though the ratepayers finance the mailings and the PUC was required to approve the content of any solicitation or other message included).¹⁹ How can we reverse or distinguish the *Pacific Gas & Electric* case? Illinois has done so by turning to state Department of Motor Vehicles envelopes to transmit such solicitations to join and contribute. Should this model be carried further, proposed for federal regulatory advocacy, or carried to other states?

Energy Commission all allow intervenor compensation. See CAL. PUB. UTIL. CODE §§ 1801–1812 (West 1997).

18. 475 U.S. 1, 15, 21 (1986).

19. *Id.* at 25–26.

C. Imbalance: Lobbyist Regulation and Tax Code Favoritism

In many states advocating before agencies (especially on rulemaking issues) is considered lobbying and is regulated as a part of general legislative lobbying regulation. However, attorneys often are excepted from designation as lobbyists and do not have to register. What provisions would an optimum agency lobbying statute include?

As discussed in the Session on Legislative Reform, can we partly redress the current imbalance of advocacy-favoring profit-stake interests through the tax code? Currently, we allow business and profit interests to deduct monies spent on lobbying as a necessary business expense. This means that lobbying by profit-stake interests is twenty to forty percent subsidized by other taxpayers who must make up the foregone taxes. Meanwhile, lobbying by those who lack a profit-stake, but whose interest is considered charitable, are denied or limited in their access to our legislators. Should this situation not be reversed? Why not end any deductibility for lobbying expenses related to business and profit interests and allow an assured percentage (for example, twenty-five to fifty percent) of the budget of nonprofits or qualifying charitable entities to be expended for such advocacy?

Should we pay compensation to those individuals who provide information to legislators on behalf of general, disadvantaged, or future interests? How?

D. Procedural Fairness

Related to information imbalance is the practice of many agency officials of allowing private meetings with persons financially interested in pending official business. Such *ex parte* contacts are sometimes limited where adjudications are pending, but rarely is this the case for rulemaking. Regulations are usually adopted under administrative procedure acts that require hearings. But how important are such public hearings if private discussions without public examination or questioning have already occurred and if commitment of support is often already obtained? If *ex parte* limitations are not imposed, should legislators be required to disclose their contacts with parties interested in their official decisions?

V. PUBLIC ACCESS

Agencies, particularly at the state and local level, have little public visibility in the normal course of their operations. They often deal in arcane subject matter. At the local level such agencies are commonly fragmented into many specifically empowered bodies. For example, Los Angeles County includes over 350 separate special districts, each with

its own boundaries and governance. However, such dispersion does not mean the decisions made do not have broad public impact. The decisions of a water district agency are critical to the supply and price of water. The proceedings of a port authority often affect the most valuable and environmentally sensitive land in a region.

Three statutes extant in some jurisdictions can interact to provide greater public visibility for agencies. Where such visibility exists, officials are more likely to receive input from broader interests, and long-range implications are more likely to be considered. The first type of statute, called “sunshine statutes,”²⁰ generally includes “freedom of information” or public records laws assuring public access to documents produced by public agencies at marginal cost and without a standing requirement. So-called open meetings laws²¹ are the second type of statute; these laws require agencies to publish their meeting agendas in advance of meetings and to include discussion of all matters upon which action can or will be taken. Closed sessions are allowed only for specific purposes. The last type of statute, an administrative procedure act (APA), federally and in every state,²² spells out how the agency is to conduct its important rulemaking and adjudication (for example, discipline of licensees) functions. At least as to rulemaking, these statutes also provide for public input, and some such statutes give any person the right to propose a rulemaking proceeding—a much unused tool for public interest advocates, given the scope and impact of possible rulemaking.²³ Should the federal APA be amended to provide similar public input? Public standing to intervene (for example, to remove drugs before the FDA)²⁴ can serve as a check on inadequate regulation. What other measures might stimulate open proceedings, public votes, and accountability?

20. See *supra* note 15.

21. See, e.g., The Bagley-Keene Open Meeting Act, CAL. GOV'T CODE §§ 11120–11132 (West 1992 & Supp. 2003); The Brown Open Meeting Act, CAL. GOV'T CODE §§ 54950–54962 (West 1997 & Supp. 2003).

22. Administrative Procedures Act, 5 U.S.C. §§ 551–583, 710–706, 1305, 3105, 3344, 5372, 7521 (2000); MODEL STATE ADMIN. PROCEDURE ACT §§ 1–14 (1981).

23. See, e.g., CAL. GOV'T. CODE §§ 11340.6, 11340.7 (West 2002).

24. See, e.g., Letter from Public Citizen, to Jane Henney, M.D., Commissioner, Food and Drug Administration (August 31, 2000), available at <http://www.citizen.org/publications/release.cfm?ID=6734> (last visited Feb. 1, 2003).

VI. MEDIA ATTENTION

Even more than the legislative and court fora, agencies operate outside of the public eye. The media rarely cover the decisions of agencies (especially state agencies) unless they happen to affect a matter already within the interest of the public. The more visible these agencies, the more likely broader public concerns will have weight in decisionmaking, and particularly in setting the agency's agenda. How do we stimulate media coverage of agency governance? How do we overcome the media war over regulation, even of food and drug safety, as a reflection of the "government as devil" orientation of many commentators and political leaders?

VII. REGULATORY AUTHORITY

Many agencies are paper tigers, lacking adequate authority to collect needed information or to impose predictable and deterrence-producing sanctions. What other structural measures should be employed to allow agencies to police effectively, particularly in areas where error portends irreparable harm?

The materials distributed for this Session include another aspect of inadequate regulatory authority, the political reversal of protections by executive decree. The question to be asked in this arena is whether the removal or delay of such protections should be subject to some of the same due process requirements as those imposed on their adoption.²⁵

A pending case²⁶ may decide the scope of agency discretion under broad enabling statutes to regulate (in this case, ozone and soot levels). To what extent is such agency discretion necessary to regulatory authority? Should we require more specific, ascertainable legislative standards to make court mandated enforcement possible where agencies are guilty of nonfeasance? Is it better to rely on broad agency authority so that more specific safeguards are not easily evaded where they are more inflexibly embedded in a statute?

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VIII. BACKGROUND ON PANELISTS

Joan Claybrook has served as president of Public Citizen since 1982.

25. Press Release, Public Citizen, Bush Delay of Critical Consumer, Worker and Environmental Safeguards Has Wide-Ranging Implications (Jan. 30, 2001), available at <http://www.citizen.org/pressroom/release.cfm?ID=572> (last visited Feb. 1, 2003).

26. See Joan Biskupic, *EPA Pollution Standards Defended*, USA TODAY, Nov. 8, 2000, at 21A.

Public Citizen is a nonprofit research, lobbying, and litigation organization founded by Ralph Nader that seeks to improve the health and safety of the public.²⁷ Claybrook is also the founder and director of Public Citizen Congress Watch, which was created to lobby for enactment of legislation on health, energy, and protection of consumers in the marketplace.

Previously, Claybrook was appointed by President Carter as Administrator of the National Highway Traffic Safety Administration (NHTSA), the agency charged with issuing motor vehicle safety and fuel economy standards, recalling defective vehicles and equipment, providing assistance to states to improve highway safety programs, and developing technical vehicle safety information for consumers.

Claybrook currently serves as chair of the Georgetown Law Center Board of Visitors, co-chair of Advocates for Highway and Auto Safety, and co-chair of Citizens for Reliable and Safe Highways. She holds many board positions, including positions at the American Judicature Society, Consumers Union, Goucher College Board of Trustees, Citizens for Tax Justice, and Trial Lawyers for Public Justice. She is the recipient of several distinguished service awards, including the honorary Doctor of Public Service Award from the University of Maryland, the Philip Hart Distinguished Consumer Service Award from the Consumer Federation of America, and the Excellence in Public Service Award from Georgetown Law Center.

Claybrook has authored numerous books and articles about consumer and safety issues, including *Retreat from Safety: Reagan's Attack on America's Health*;²⁸ *Freedom from Harm: The Civilizing Influence of Health, Safety and Environmental Regulations*;²⁹ and *Women in the Marketplace*.³⁰

David G. Hawkins has directed the Natural Resources Defense Council's (NRDC) Air and Energy Program, which covers energy policy reform, climate change, and Clean Air Act implementation, since 1990.³¹

27. See generally Public Citizen, at <http://www.citizen.org> (last visited Feb. 1, 2003).

28. JOAN CLAYBROOK, *RETREAT FROM SAFETY: REAGAN'S ATTACK ON AMERICA'S HEALTH* (1984).

29. DAVID BOLLIER & JOAN CLAYBROOK, *FREEDOM FROM HARM: THE CIVILIZING INFLUENCE OF HEALTH, SAFETY AND ENVIRONMENTAL REGULATION* (1986).

30. Joan Claybrook, *Women in the Marketplace*, in *CORPORATE VICTIMIZATION OF WOMEN* 111 (Elizabeth Szockyj & James G. Fox eds., 1996).

31. See generally National Resources Defense Council, at <http://www.nrdc.org/> (last visited Feb. 1, 2003).

Hawkins began his work in public interest law upon graduation from Columbia Law School in 1970. After working for the Stern Community Law Firm in Washington, D.C. for one year, he joined NRDC as an attorney in 1971. With NRDC attorney Dick Ayres, Hawkins began NRDC's Clean Air Project, which has monitored and shaped the design of the federal Clean Air Act since the law's passage.

In 1977 Hawkins was appointed assistant administrator for Air, Noise, and Radiation at the U.S. Environmental Protection Agency during the Carter administration. He returned to NRDC in 1981 and worked throughout the decade primarily on reauthorizing the Clean Air Act, including the development of a national program to combat acid rain. Congress eventually passed a much strengthened law in 1990. NRDC was a major architect of all of its provisions.

Jim Hightower is an author, radio commentator, public speaker, and political sparkplug. Hightower has spent three decades battling Washington, D.C. and Wall Street on behalf of consumers, children, working families, environmentalists, small businesses, and just plain folks.

Hightower takes on the powers that be on behalf of the powers that ought to be in his daily radio commentaries that are broadcast on over sixty affiliates nationwide. He also publishes an award winning monthly action newsletter, the *Hightower Lowdown*, providing his unique populist insights on the issues of the day and giving readers connections for agitating and organizing around the issues. Hightower's best-selling books include *There's Nothing in the Middle of the Road but Yellow Stripes and Dead Armadillos*³² and *If the Gods Had Meant Us to Vote They Would Have Given Us Candidates*.³³

Hightower began his career in Washington, D.C., where he served as legislative aide to Texas Senator Ralph Yarborough, worked on rural development issues for the Rural Housing Alliance, and founded and directed the Agribusiness Accountability Project, for which he wrote several books and testified to Congress about the human costs of corporate profiteering and the value of sustainable, healthy, cooperative farming.

Under Hightower's leadership as editor, the *Texas Observer* pioneered hard-hitting investigative articles on corporate power; and, because of this, Hightower was awarded the Texas Farmers Union's "Outstanding Journalist Award." He was narrowly defeated when he ran for railroad commissioner, served as president of the Texas Consumer Association, and was twice elected as Texas Agriculture Commissioner (from 1983 to

32. JIM HIGHTOWER, *THERE'S NOTHING IN THE MIDDLE OF THE ROAD BUT YELLOW STRIPES AND DEAD ARMADILLOS* (1997).

33. JIM HIGHTOWER, *IF THE GODS HAD MEANT US TO VOTE THEY WOULD HAVE GIVEN US CANDIDATES* (rev. ed. 2001).

1991) where he used his agency to help bring social justice and economic opportunity to all Texans. Hightower has also served as chair of the National Democratic Party's Agriculture Council and chair of the Financial Democracy Campaign.

David A. Swankin has been president and CEO of Citizen Advocacy Center (CAC) since 1994. CAC is a training, research, and support network for public members of health care regulatory and governing boards and was created to equip public members to lead their boards toward serving public policy goals more effectively and efficiently.³⁴

Swankin is also a partner in the law firm of Swankin & Turner. He has a broad background in both government and public interest advocacy. His government career included assignments as the first executive director of the White House Office of Consumer Affairs as well as director of the Bureau of Labor Standards and deputy assistant secretary at the U.S. Department of Labor.

Swankin has provided legal services to numerous public interest and professional organizations, including serving as special counsel to the National Association of Consumer Agency Administrators, general counsel to the National Consumers League, and special counsel to the Consumer Federation of America. He was also a member of the original National Advisory Council to the Consumer Product Safety Commission. He served as a commissioner on the Pew Health Professions Commission during 1997 and 1998.

Swankin received an A.B. degree in Economics from Brandeis University, an M.S. in Economics from the University of Wisconsin, and a J.D. from George Washington University School of Law. He has also served on the faculty of the University of Southern California (Washington, D.C. campus).

Dr. Sidney Wolfe met Ralph Nader in Washington, D.C. at a meeting of the American Patients Association in 1968. Wolfe began advising Nader on healthcare public policy issues and helped in the recruitment of medical student volunteers who worked for Nader. Wolfe then set up the Public Citizen's Health Research Group and has served as its director since 1971.³⁵ Among the successes of the group are the banning of the drugs, Phenformin, Orafles, Tandearil, and Suprofen; the requirement that aspirin

34. Citizen Advocacy Center, *About CAC*, at <http://www.cacenter.org/about.htm> (last visited Feb. 1, 2003).

35. See generally Public Citizen, *The Health Research Group*, at <http://www.citizen.org/hrg> (last visited Feb. 1, 2003).

products have a label warning that children and teenagers may develop Reyes Syndrome through the use of aspirin in the treatment of colds and flu; forcing a smokeless tobacco warning on tobacco labels and in advertisements; and studies of medical malpractice and doctor discipline.

Wolfe has also been an adjunct professor of Internal Medicine at the Case Western Reserve University School of Medicine since 1995 and is currently a member of both the American Federation for Clinical Research and the Society for General Internal Medicine. His awards include a 1990 MacArthur Fellowship by the John D. and Catherine T. MacArthur Foundation.

Wolfe studied chemistry at Cornell University in Ithaca, New York. His medical degree is from Case Western University in Cleveland, Ohio, and his internship and residency were in internal medicine.

IX. PANEL DISCUSSION³⁶

ROBERT FELLMETH:

The final Session here concerns executive branch agencies. We know that many societal and market abuses may be most effectively addressed by the executive branch, particularly by regulatory agencies. Unlike personal injury or mass consumer tort action, which assess damages for injuries post hoc, agencies may be able to prevent damages through protective intervention or market adjustment. However, the theoretical promise of a more preventive oriented societal mechanism has been, to some extent, compromised by conflicts of interest, job interchange problems, campaign finance influence, problems with the rules by which these agencies operate, their statutes, and other features which the panel will discuss.

We are privileged to have as moderator for this panel Joan Claybrook, who has served since 1982 as president of Public Citizen, a nonprofit research, lobbying, and litigation organization founded by Ralph Nader. She was also the founder and director of Public Citizen's Congress Watch, which was created to lobby for enactment and legislation of health, energy and protection of the consumers in the marketplace. Most important of all, she directed the profiles of the Nader Congress project. Previously, she was appointed by President Carter to direct the National Highway Safety Administration. She is the recipient of too many awards to mention.

We have someone on this panel who headed a federal agency;

36. This Part has been edited to remove the minor cadences of speech that appear awkward in writing and to identify significant sources when first referred to by the speakers.

someone who headed a state agency; someone who advocates before federal and state agencies; and we cover consumer, environmental, health, and other public interest issues substantively with this panel.

JOAN CLAYBROOK:

Thank you very much, Bob. It is a pleasure to be at this conference. I have truly enjoyed the chance to mix with so many wonderful people and also to learn. I am so pleased that this panel has such strengths. We actually have three former regulators who all went back and worked in the public interest—David, Jim, and myself—and that is a rare animal.

We all know that regulations can make such a difference in the lives of everybody. For example, just look at the reaction to Bush's initial effort to get the ergonomics rule, which took over ten years to develop, overruled in the Congress. Look at the carbon dioxide standards, where he decided to reverse his position from his campaign rhetoric, and look at the arsenic-in-water standard. Already, three important safety standards undermined with more to come. So understanding the regulatory process is essential for consumers.

We are going to address eight issues, and I want to tell you what the eight issues are, and then each panelist is going to take a crack at them from their own perspective and experience.

The first issue is the rules of decision and the procedures under which these agencies operate. Such things as the Administrative Procedure Act;³⁷ access to information, the Freedom of Information Act;³⁸ ex parte rules, revolving door, and the role of the business community in the use of these rules. We are going to look at procedure as it is intended, as neutral arbiters and assistants to the regulatory process. We are going to discuss the politicization of these rules and their use by the business community to try to undermine regulation.

The second issue is the importance of the statutory underpinnings of the regulatory process. How the statute is written makes a huge difference, and those of us who have been regulators can certainly tell you that; and I think those of you who are litigators certainly know that.

Third is going to be the role of international trade in the regulatory process, in terms of the technical barriers to trade and harmonization

37. Administrative Procedure Act, Pub. L. No. 101-552, 104 Stat. 2736 (codified as amended in scattered sections of 5 U.S.C.).

38. 5 U.S.C. § 552 (2000).

among different countries. This is an important issue for the integrity of U.S. agency standards.

Fourth is the role of litigation in the regulatory process, forcing agendas on agencies, overruling revocations of standards, overruling standards, and giving government agencies backbone.

Fifth, we are going to talk about appropriations and the role of money, because it has been a critical issue. Many of these agencies have been severely underfunded—a tactic common in the Reagan years. And then, there have been riders on appropriations bills; David Hawkins is an expert in some of the terrible riders, for example, riders to stop any issuance of fuel economy standards for SUVs for six years now.

Sixth is the role of the agency administrator and the importance of that role. How are people selected? Do they have to win approval of the legislature? How much discretion do agency heads have?

Seventh is the media, the role of the media and how it can make or break a government agency and also make or break decisions on rules.

Number eight is constituencies, the role of outside constituencies, whether it is attorneys general, whether it is citizen groups, whether it is citizens themselves, or whether it is funding to help citizens participate.

So with that very brief introduction, I would like to open a discussion, maybe starting with David Hawkins and coming to my left, on the role of procedure in the regulatory process.

DAVID HAWKINS:

Sure. The initial set of rules that were enacted prior to the early 1970s are critical to open government and empowering citizens. They include, among other things, the Administrative Procedure Act, the Freedom of Information Act, and the right of judicial review under the Administrative Procedure Act. I have had occasion to go and teach courses in places like Russia and Thailand, and it is a real eye opener to those societies to have them hear about rights of access and government accountability—the Freedom of Information Act (FOIA) that we have. Those things have been and continue to be tremendously empowering. I am sure others will have much more to say about the basics of those provisions.

One comment I can make is that the opposition is figuring out ways to turn those tools into a double edged sword. Many law firms specialize in APA efforts to defeat rules that their clients do not like. A recent example of the use of these tools to harass is the extension of the FOIA to data access under something called the “Shelby amendment.”³⁹ Here, in an attempt to defeat tighter air quality standards issued in 1997, the

39. 18 U.S.C. §§ 2721–2725 (2000) (amended as of Oct. 9, 1999 and effective June 1, 2000).

industry said: “We want access to the data from the underlying research studies. And that means we want the patient diaries for these underlying research studies.” They succeeded in getting it enacted into law in 1999, a requirement that FOIA applied to any data collected in a federally funded research program so that it would have to be made available. There is a huge controversy about this. Data that underlies an industry study that is submitted to the agency for the purposes of getting a drug approved, or for purposes of getting a new pollution facility permit, is not subject to FOIA under this provision. It only applies to data that the government spends money to develop, so you can easily see the one-sided nature of this. The industry gets to tear apart studies that the government relies on in order to protect the public, but the public doesn’t get to analyze the data that the industry uses to support their regulatory initiative.

JIM HIGHTOWER:

I will just add a very brief comment to that, as one who is on the inside actually trying to do something—rather than to prevent something from happening. There is another problem that arises with these rules of access. You will find industry trying to impose ever greater rules of access that tie you up into knots to where you can’t do anything. So you have to have both rules that allow access, but then be wary of efforts by lobbyists and industry groups to clog the system so much with rules that you are spinning your wheels on a constant basis to get around them.

JOAN CLAYBROOK:

I would just like to say two things. One, it suddenly occurred to me that some people may not know what the heck the Administrative Procedure Act is at the federal level. It is a law that requires government agencies, when they want to issue a regulation, to go through certain steps. They are to put out a proposal, publish it in the federal register, allow time for the public to comment on it, accept comments, and put those comments in a public docket, so that everyone can comment on everyone else’s comments.

When I was a regulator, I limited my comments to fifteen pages, you couldn’t submit more than fifteen pages in any comment to our docket because the industry would submit 500, and then you could never figure out what they were saying. After the comments to the docket come in, the agency has authority to issue a final rule. Now, that is an informal

process. There is a more formal process for agencies with multiheaded commissions, such as the Federal Trade Commission, where the process is much more formal, with cross-examination and extensive hearings.

Some agencies also have hearings as a part of this process, if they think that it is important to the public, and they often have field hearings as well as hearings in Washington, D.C. There is also a Federal Advisory Committee Act which puts some limits on the way that advisory committees can be put together.⁴⁰ It was passed as a reform in 1972, because a lot of agencies have the industry advisory committees, and they were not public. No one knew when they met—they were like an insider back door into the agencies, a lot of buddy-buddy stuff together. It required balanced advisory committees, public advisory committees. The committees had to be chartered, and they had to publish their agenda in advance. So that was another type of reform.

These rules were designed to make sure the public had access. I would just like to mention (because I'm a lobbyist I have to lobby for one minute) that the President has indicated that he is going to nominate a gentleman named John Graham to be the new head in the Office of Management and Budget, which is a part of the White House. In the Office of Management and Budget they have an office called the Office of Information and Regulatory Analysis, and it is through this office that many of the rules have to pass, particularly the most controversial and costly ones, before they can actually be issued. Vice President Bush, and also Dan Quayle as Vice President, used this office to stop health and safety and environmental standards by saying that they had not met the cost-benefit standard or that they had not had a sufficient risk analysis. We figured out that this guy was going to be appointed, so last week we published a report of a hundred pages on all of his bad deeds and how he has represented the hundred biggest corporations in America—although he works out of the Harvard School of Public Health. It is on our Web site as well, at www.citizen.org. I also have a handout of our news release and the letter to the Senate, in case anyone wants a summary.

Graham is a proponent of the politicization of these rules. He insists that we should look at all standards at one time, put all the issues on the table, and that we should choose the ones that would be the best use of resources. For example, instead of tackling dioxin, we should get kids to wear bicycle helmets. That would be cheaper and more efficient to save lives. Of course, there is a total irrelevancy between the two, but that doesn't matter. That is his risk-versus-risk analysis. His whole principle is: "don't criticize regulation, just send people in the wrong direction."

40. Federal Advisory Committee Act, Pub. L. No. 92-463, 86 Stat. 770 (codified as amended in scattered sections of 5 U.S.C. app.).

So that is what we can expect in the next three or four years, and, obviously, we have some initiatives to take to deal with his future attempts to misuse the rules.

DAVID SWANKIN:

So we all would agree that we think it is okay for Joan to have violated her own fifteen-page rule?

JOAN CLAYBROOK:

Oh, no, no, the first part is fifteen pages.

JIM HIGHTOWER:

What I was wondering was, how did your fifteen-page rule survive Buckley?

DAVID SWANKIN:

Most of my observations are going to be based on observing around the country the system that we have in place to regulate the occupations and the professions and, in particular, the health professions. We have, maybe, 1000 different agencies spread over the fifty states that do it. About 800 different professions and occupations are licensed in this country. A lot of people cannot do what they do at work without a license. So licensing has a tremendous impact on what it is that people can do.

On the days that I want to be optimistic, I could look at the best of the best. I could look at the fifty states and, on every one of the issues that matter, find one or more enlightened examples. Take ex parte. Florida (and who thought I would be saying something good about Florida) has the most rigid rule to prohibit ex parte communication in everything regulatory boards do.⁴¹

JOAN CLAYBROOK:

What is considered ex parte in Florida?

DAVID SWANKIN:

No board may make any kind of decision in private, without everybody present and there. They cannot have a private meeting with

41. FLA. STAT. ch. 120.66 (2002).

anybody. They cannot even have a meeting or conversation. It is not that it is put “on the record” as in some jurisdictions—they just can’t do it. They make decisions from comments made in public meetings—no private lobbying.

JOAN CLAYBROOK:

You mean with certain lobbyists and industry advocates?

DAVID SWANKIN:

They cannot meet with lobbyists; they cannot meet with consumer groups. They have to do everything out in the open. On the other end of that scale, there are still boards today that go into executive session. They open the meeting, they go into executive session, they do what they do, and then they come back in and say: “the executive session is over, any other comments?” Meeting is over. That still happens today in some of the states.

So it is hard to speak generally about what is going on, because the range is so great. So I would like to concentrate on the bad parts about it today, so nobody automatically assumes that these are the things that are happening everywhere. But they are happening in enough places to be concerned about it.

There still is an enormous amount of *ex parte* communication to these regulatory boards. And the other thing, by way of background for those of you that do not know it, is that much state regulation (that has no real counterpart at the federal level) is self-regulation. Sidney knows this well from his work with the regulation of physicians—they are regulated by themselves under the current law. If they did not have the power of law behind them, they would be violating antitrust law every day of the week. They have the power to allow you to practice by giving you the license in the first place; they have the power to take the license away in the second place, which they never could do were they private associations.

The third thing you have to understand about this system is that none of these laws came about because the legislatures looked at what was needed to protect the public health and safety and said: “We’ve got to have medical boards; we’ve got to have nursing boards.” These boards came about, with very few exceptions, because the profession asked to be regulated. Until the Second World War these boards were made up exclusively of the profession—one hundred percent. They had the profession regulating itself as the only form of regulation. That is where most of the problems we have come from.

SIDNEY WOLFE:

Because we are research based, we rely heavily on the Freedom of Information Act and the Administrative Procedure Act and the Federal Advisory Committee Act to get the data to challenge decisions. Whereas the Freedom of Information Act has counterparts in most states, the Federal Advisory Committee Act does not. This may sound like the topic of litigation, but I will mention it here, because it is a way of using the rules of decision for access to data. The Federal Advisory Committee Act says that there should be meaningful public participation in federal advisory committees: they have to post notice of the meetings in advance; they have to be presumptively open.⁴² Since this law was passed in 1972, they rarely close these meetings. There also has to be a section devoted to public participation. Public members such as ourselves, or anybody else, have to have a chance to stand up and say something. Recently, with the help of our litigation group, we have used a combination of the Federal Advisory Committee Act and FOIA to sue the Food and Drug Administration to force them to disclose data in advance of its decision making on drugs. As a result, when we walk into the advisory committee meeting now, we have seen the unpublished data from the industry and, more importantly, from the FDA's own analysis. This first happened in January of 2000, and already it has made an enormous difference. So I cannot stress enough how these rules can matter.

At the state level and to some extent at the federal level, one underused aspect of these sunshine rules is the Freedom of Information Act. The Jeffersonian concept that "information is power" is resonant in that law. I am frequently appalled to see groups federally (and at the state level) working on issues where we know data exists that would support their contentions and give them a win. I just urge people to use the Freedom of Information Act more. We have a major portion of our litigation group devoted to it, and they have served as a consultant or co-counsel with many groups to try and bust this open. I think there has been enormous progress made in that direction in the face of the worst kinds of administrations.

42. Federal Advisory Committee Act, Pub. L. No. 92-463, 86 Stat. 770 (codified as amended in scattered sections of 5 U.S.C. app.).

JOAN CLAYBROOK:

Actually, Public Citizen has published a number of books that Sid has written using FOIA documents. It has made us a lot of money, so I urge you to—

SIDNEY WOLFE:

That is not why we did it.

JOAN CLAYBROOK:

No, that is not why we did it. We did it to inform the public, and to make money. Something that I failed to say in the very beginning is that regulations that an agency issues have the effect of law. What an agency does is enforceable under the law in exactly the same way as is the underlying legislation. Essentially, it is an extension of the role of the legislature in the issuance of these rules, and they can be enforced, and companies can be fined if they fail to abide by them. They can be required to recall vehicles that do not meet the prescribed standards, and so on.

One of the things that I asked these panelists and myself to focus on is remedies. I would just like to start off by saying that one of the real advantages of the Web in many of these regulatory agencies is that, rather than have dockets filled with information that you can only get by going down and visiting the agency, now they have put the information on the Web. Now a much larger constituency across the world can take a look at that information. And if you are interested in looking at a particular company and what positions it is taking on rules pending before agencies, you can do it. You can look, let's say, at what General Motors said to the Civil Rights Commission and what they said to the Department of Transportation, what they said to the EPA, and so on. You can really do some fascinating work. It is a deeper participation in the decisionmaking process, because you have access to what the companies, as well as what the public interest groups, have said.

SIDNEY WOLFE:

Could I just add something? This lawsuit that I mentioned we brought against the FDA in advance of the advisory committee meeting—its success depends upon information. And onto the FDA Web site goes all the data, industry data, and the FDA data, analyzing the safety or effectiveness of this drug.

JOAN CLAYBROOK:

It sounds like you agree with the Shelby amendment, Sid.

SIDNEY WOLFE:

Pardon? No. This is not the raw data, it is the summary data. The problem with the Shelby amendment is that it gets down into personal things, and it provides the kind of data to tie up things for years and years.

JOAN CLAYBROOK:

I have a feeling there are going to be some privacy lawsuits on the Shelby amendment. Let's go now to the politicization of these rules. I think David is the world's expert on this, David Hawkins, that is.

DAVID HAWKINS:

Well, I am one of the many victims of what has happened in the last thirty years. Just to give you a real quick snapshot, in 1970 the EPA and the Occupational Safety and Health Administration (OSHA) were created, and they were given broad powers to improve safety in the workplace and clean up the environment. For a couple of years they were actually allowed to do their job fairly efficiently. But very quickly industry figured out how to proceduralize those authorities in what I call the "regulatory strangulation process." Another image that might be useful to you is sort of the "hardening of the arteries." Industry has been figuring out ways to use procedures to pump cholesterol into the arteries so that it builds up to the point where the ability to get a rule out is so constricted that many agencies come close to having a heart attack before they are actually able to issue one.

Others will talk about some of the specifics. I have given you a couple of handouts because one of the remedies to this is to know the opposition and to get involved. So this is why you have a couple of pieces of paper at your place from something called the Center for Regulatory Effectiveness.⁴³ This is a Washington, D.C. operation that specializes in dreaming up new ways to get in the way of regulation. One of these pieces of paper is a handy list of the many executive orders and laws that have been enacted that are used by industry lawyers to prevent issuance of rules or to overturn them when issued.

But let me mention that all of you can actually do something about this because of a new law that was just passed called the Data Quality

43. *See generally* The Center for Regulatory Effectiveness, at <http://www.thecre.com/> (last visited Feb. 1, 2003).

Law.⁴⁴ You have received a two-sided piece of paper on this. What this law does is give to OMB (which office, you have heard, is going to be headed by John Graham) the authority to establish minimum standards for any data that are distributed by a federal agency. As to any data that does not meet the OMB quality criteria, any interested person can force the agency to remove that data from public availability. And if you think that this may not have much teeth, go to the CRE Web site, and you will find draft regulations that they have already conveniently written for OMB to implement. CRE folks are good friends of Mr. Graham.

So we can expect to see OMB rules under this Data Quality Law by September of 2001. I am just going to give you a couple of quick highlights to show you what is at stake. These draft rules define federal data as any data created or funded by a federal agency. So any of you who get federal grants and produce reports, your data can be affected by this petition process, and a petition could be issued in a way that could require the agency to somehow prevent the publication of a report. That is one possible outcome of this. The second is that data under these draft rules are considered to be biased if they use conservative or upper bound estimates of risk. If there is a lot of uncertainty about what the risk is from exposure to a chemical (like arsenic) and the agency decides that it is going to fully display the range of uncertainty by using upper bound estimates as well as best estimates, the statute may be violated. Lower bound estimates, by the way, are not considered to be biased under this.

SIDNEY WOLFE:

Sounds like a biased decision.

DAVID HAWKINS:

Yes. Again, that could be a basis for petitioning to have this data removed. And here is the kicker that I think is quite interesting in these draft rules: the draft rules have an emergency provision where, if the petitioner alleges the threat of immediate irreparable harm, the agency shall immediately desist from dissemination until the petition is decided and until any judicial review of that petition is decided. So if this law had been in place when the secondhand smoking information was made available to the public, its disclosure would have been barred. The tobacco industry would have used this, they would have alleged irreparable harm, and they would have been able to go get a temporary restraining order under the proposed rule. This is a classic example of prior restraint to free speech, except that now it is to be applied to regulatory agencies.

44. Consolidated Appropriations Act of 2001 § 515, 44 U.S.C. § 3516 (2000).

So my message to you is, take this piece of paper home with you. You have all got computers; go to the Web site and join with us in getting involved to raise bloody hell about it.

JIM HIGHTOWER:

Well, I would just add that there is a politicization of rules and a politicization of laws. It is certainly nothing new. It is well discussed in this recently published book that is just jam-packed with information. It is extraordinarily well written, and it happens to be written by me.

I refer to the creation of the Interstate Commerce Commission back in 1887, a reform that had been pushed by Grover Cleveland as part of his campaign for President. It was advanced ostensibly to regulate railroads, but railroad executives were told by Richard Olney, who was a railroad lawyer, not to worry about this new agency, the Interstate Commerce Commission. Mr. Olney would soon become Grover Cleveland's Attorney General. He assured the railroads that the Commission is or can be made of great use to the railroads. He wrote: "It satisfies the popular clamor for a government supervision of railroads, at the same time that the supervision is almost entirely nominal. . . . The part of wisdom is not to destroy the Commission, but to utilize it."⁴⁵ And there we have writ bold the history of much regulation.

To pick up on something that David Swankin was saying earlier, that most regulation comes from the industries themselves. I think of country ham. I do not know if there are any country ham lovers in this room, but in the Appalachian Mountains, wonderful hams were cured by complicated processes in barns and elsewhere until about the 1970s. Then IT&T bought the Smithfield Ham Company and pushed through the FDA new regulations that required aluminum tables and all sorts of new equipment in order to get certified as a safe country ham producer. The result cleaned out thousands of mom-and-pop country ham producers and turned the industry over to about three companies that now manufacture country ham. It had nothing to do with the safety of country ham and everything to do with the monopolization of country ham.

So politicalization through regulatory processes is long established in our history. We must, as Dave Hawkins was just saying, not only be

45. Letter from Richard Olney, to Charles E. Perkins (1892), in Louis L. Jaffe, *The Effective Limits of the Administrative Process: A Reevaluation*, 67 HARV. L. REV. 1105, 1109 n.7 (1954).

wary of it, but go on the offensive, which is what this conference is all about. Go on the offensive to change those rules with more freedom of information, more right to know type of legislation, more Internet information. I don't know why we don't have streaming video of every regulatory proceeding, so we don't have to go to Washington to watch it happen. Have it right there. If nothing else, it will appall the people of America. Just think about the power of C-Span when thousands, millions of Americans for the first time actually see a congressional hearing and think, "my God, my senator has the IQ of a dust bunny." It is very radicalizing to have this happen. The more empowering we can do of people themselves, not just through organizations, but the people themselves, the better off we are going to be.

JOAN CLAYBROOK:

One of the political uses of health and safety standards is in the tort system. For example, the auto companies always say that they meet all government standards whenever they are sued, no matter how badly defective the vehicle is. Of course Ford and Firestone said that as to the Firestone tire and the Ford Explorer. Luckily, that is an example of the role of media, which turned that claim on its head.

I would say that one of the ugly pieces of the politicization of the regulatory process has been the Regulatory Review Act, which was passed in 1996.⁴⁶ Nobody paid a whole lot of attention to it. Back in the 1970s, there was something called the congressional veto. Public Citizen went to court and got that overruled in 1983 in *Chadha*.⁴⁷ Alan Morrison brought that case. We thought we were finished with having Congress get involved as to whether these regulations should be retained because Congress was using this veto to overrule regulations or safety standards issued by government agencies. The Congressional Review Act⁴⁸ is a variation of that—a constitutional variation. If a regulation is issued, it has to go to Congress for sixty days, and if Congress decides that they want to deep-six it, they can pass a bill through the House. If the President signs it, the rule is voided. Well, Clinton was not going to sign anything to void a rule that came out of his agencies, so it did not operate for years. But all of the rules issued in the later days of the Clinton administration are now being sent through this congressional review process by members of Congress. Of course President Bush is going to sign them; he has already done so with the ergonomics rule.

46. Small Business Regulatory Enforcement Fairness Act of 1996 § 251, 5 U.S.C. §§ 801–808 (2000).

47. *INS v. Chadha*, 462 U.S. 919 (1983).

48. Small Business Regulatory Enforcement Fairness Act of 1996 § 251, 5 U.S.C. §§ 801–808 (2000).

The other thing that this Congressional Review Act does, which I think people had not focused on, is that it undermines the role of the courts and litigation. Because, if industry can get rid of the ergonomics rule by having it revoked by the Congress, then there is no battle in the courts over whether this rule was properly issued and whether there is a substantial basis for it. The industry does not have to bother with evidence or a factual argument, and public interest groups cannot oppose the industry's attack on it. So that is a very serious new law that was passed.

Then there is one that has not passed, the Regulatory Reform bill, which is actually a deform bill. We have been battling it for about seven years now. It was Bob Dole's bill, and he was going to get elected to Congress on the money he raised from those paying him to offer it. He got a lot of money, but luckily he did not get elected to the Presidency. There are still attempts to pass this bill, and our friend John Graham has been a major advocate of this legislation. It would change all the rules of engagement in the regulatory process in a very negative fashion.

DAVID SWANKIN:

I think throughout this conference we assume that we are the good guys, and in a lot of the panels the bad guys are corporate interests. In my experience, there is another bunch of bad guys out there from the professions, including the legal profession. The professions in the field that I know best are the people doing the things that ought not be done. The thing that upsets me a lot is that it is oftentimes done in the name of due process. I will use a federal example first.

Under the Medicare program, a Medicare beneficiary files a complaint. It is supposed to be investigated by a state peer review organization that is set up under law to review the quality of care and the utilization of Medicare dollars. It has been a flawed process. But, in the name of due process, if you file a complaint and it is investigated and determined to be valid and it was a complaint based on the substandard quality of care, the following happens: the federal government, through its peer review program, will write the physician involved and ask for permission to release the information of the investigation, including the patient's name. Unless the physician approves, the letter back from the agency will say: "We've investigated it, and your complaint is valid, but we cannot tell you any more, because due process does not allow us to tell you about our resolution." The result is a kind of medical profession

veto power, in the name of due process, over disclosure of a final resolution, if any.

In many states legislation has been introduced recently that affects this discipline process. If the agency has not completed its investigation and decided to bring a case within 60 days, 90 days, or 180 days, a short time period, the agency is required to drop the case. It is worse than a statute of limitations. The people who push these types of legislative proposals through in the name of due process have correctly complained that agencies take too long to do their work and have incorrectly said that if they do not do it, we are going to punish them by rendering them impotent, which for some of them is a desired state of being. It is very scary.

SIDNEY WOLFE:

A couple of examples to pick up on what David just said, we actually brought a medical malpractice suit in Florida on behalf of a federal Health and Human Services employee whose mother had died. We argued that the due process that was afforded to the doctor to be able to say “no” to making public the facts of his being found incompetent did not really mesh with the law. Although we won that case, it remains to be seen whether we are going to overturn the entire process. He will get his information, but the systemic solution is lacking.

I have a couple of examples that Bob Fellmeth had mentioned as he encouraged us to talk about various topics. Two things clearly fall under this politicization of standards process. One is conflict of interest. Financial conflict of interest is destroying the regulatory process in terms of FDA’s approval of drugs. If you were to own \$100 million of stock in a drug company and you were the sole actor running the two clinical trials upon which a drug from your company was going to be judged, you are not disqualified. You are not an employee, but rather merely an owner. The sky is the limit in terms of how much financial interest you can have in a company whose products you are allegedly testing.

The same is not true at the Federal Advisory Committee level, but lately at the state level as well as a federal level, agencies interpret conflict of interest provisions narrowly. The FDA has guidelines as to whether a person sitting on an FDA advisory committee has a conflict of interest. But, possible conflicts are waived over and over again by the agency. We helped a reporter from *USA Today* get data that showed that half the people on the FDA Advisory Committee had some significant conflict of interest. At the beginning of every advisory meeting, they say doctors *A, B, C, D, E, F,* and *G* have conflicts of interest, but we are waiving them, and therefore the doctors can participate in the discussion and vote.

The other thing that Bob mentioned that falls nicely into this category is self-censorship by federal employees. We would encourage other people to use the following approach in collecting information from federal agencies: we noticed that a record number of drugs were being put on the market and then banned for reasons that were known before they were approved. In other words, safety hazards were identified, and yet somehow these drugs were getting approved. So we did a study of the physicians at the FDA who work on drug approval, and we got data back from fifty-one physicians. They identified twenty-seven drugs that they said were too dangerous to go on the market, but which had been approved over their heads. Also, on the topic of self-censorship they told us that fourteen times they were told not to speak up at the Federal Advisory Committee level, because it would unduly prejudice the possibility of the drug getting approved.

So there is a wealth of information to be gained from surveying people in state or federal agencies, on an anonymous basis. We did not give out any information that could have gotten any of these people in trouble. It is relatively simple, and we would be glad to help you design survey instruments if you want to. Find out those who are working and who are witnessing the subversion of standard setting, allow them to speak out, and it can have an important impact. In the last few months, drug approvals have slowed where there is a question of safety.

JOAN CLAYBROOK:

Okay. Let's move on to the importance of statutory underpinnings. David is a genius in this area—just to put a little pressure on you.

DAVID HAWKINS:

What is at issue here, and I will use the environment as the example, is that Congress will pass legislation in response to public pressure, as Jim's quote indicated, the "clamor." As Jim's quote also indicated, if Congress can get away with handing this off to an agency that really is not accountable, then they are in the best of all possible worlds, because they responded to the public pressure for action, and yet they have insulated themselves from negative feedback from the people whom they are going to raise money from to get re-elected. So that is an ideal that Congress will try to pursue if we let them. We have tried very hard to not let them in the areas of environmental statutes.

For example, some of the things that we have done under the Clean

Air Act fall into three categories. The first is direct statutory specification of an outcome. Now, this may strike you as excessively rigid, but it does not have to be. I will use the example of the Acid Precipitation Act of 1980.⁴⁹ Here the Congress specified how many tons of pollution had to be taken out of the air. They also specified a formula in the law for allocating responsibility to individual polluters. But then they made it flexible and market-based by creating a trading regime so that the entities that were allocated responsibility to clean up could trade among themselves in order to produce an efficient result. But we did not let the EPA decide how many tons of pollution could be taken out of the air, because that would risk a ten-year peanut butter rulemaking.⁵⁰ We did not let the agency decide how the burden should be allocated among the industry, because that is basically asking them to operate like King Solomon, and they are very bad at that. They do not like to pick winners and losers, and they tend to get tied up in knots by the losers. So that is one technique.

A second technique is using deadlines for action. Congress can specify that rules shall be written and shall be adopted by a date certain. That allows us to use litigation, which is a later topic, to go in and get judicial enforcement of these deadlines.

The third technique is limits on discretion; principally, limits on what factors the agency can or must take into account when writing a rule. The flagship example of this is the health based air quality standard provision of the Clean Air Act, which just last month was upheld by the Supreme Court against industry attack.⁵¹ That law, enacted in 1970, provides that the EPA had to issue air quality standards that apply nationwide, setting the objective for cleaning up the air, and those standards should be based solely on consideration of public health, not on a calculation based on cost or economic feasibility. By limiting the agency's discretion to consider factors that would otherwise operate to weaken the outcome of a rule or make it more complicated, we can force the agency to actually carry out the political will which underlies the law. Because that is what the public wanted—a statute that said: “tell us what clean air looks like and create a program to help us get it.”

JIM HIGHTOWER:

I agree with what David said. This is what Ralph Nader was talking about yesterday. In the crafting of legislation, do it as precisely as you

49. Acid Precipitation Act of 1980, 42 U.S.C. §§ 8901–8912 (2000).

50. A reference to the decade long proceeding before the Federal Trade Commission to decide the precise percentage of peanuts necessary to allow use of the label “peanut butter.”

51. *Whitman v. Am. Trucking Ass'ns Inc.*, 531 U.S. 457 (2001).

can to achieve the public good that you are seeking. I think ultimately this is very difficult to do, but it should be pursued as much as possible. I think of Fred Harris, who is a former Senator from Oklahoma. Fred used to be in the state senate in Oklahoma, and he told of a piece of legislation that was up to change the name of the “Joe Thompson Bridge” to the “George Peterson Bridge.” It seems that Thompson was dead and gone and Peterson was popular now, and they wanted to put his name up. Fred explained that if they ever named a bridge after him, he wanted it carved into the very structure of the bridge, so that if his name was going to be taken off, the whole thing would come down. I think that is what we are talking about here.

JOAN CLAYBROOK:

I will just give a couple of examples. The Consumer Product Safety Act of 1972 said that before the agency could issue mandatory standards on a particular topic, it had to give the industry a chance to issue voluntary standards—providing eighteen months for that exercise before the agency could do anything.⁵² It severely limited the authority of the agency. It also put in a criminal provision that said you had to commit the identical crime twice before you could enforce the law, and of course that never happened.

In the auto safety statute the Congress did require the issuance of not only precrash standards (what causes a crash) but also crash-worthiness standards (what causes the injury). In fact, the requirements for that crash worthiness caused a federal district court in 1967 to issue the decision in the *Larsen*⁵³ case, in which the Eighth Circuit later found for the first time found a relationship between the owner of a vehicle (or the occupant of a vehicle who was injured) and the manufacturer.⁵⁴ The court reasoned from the obvious—the manufacturer’s design of the interior of the car could determine whether or not you were injured.⁵⁵

52. 15 U.S.C. §§ 2051–2056 (2000).

53. *Larsen v. General Motors Corp.*, 274 F. Supp. 461 (D. Minn. 1967) (holding that the manufacturer had no duty to design automobiles that would protect drivers from forces generated by head on collision, and that the manufacturer did not impliedly warrant that the vehicle would protect the driver in the event of a head on collision), *rev’d*, 391 F.2d 495 (8th Cir. 1968).

54. *Larsen*, 391 F.2d at 504 (“The manufacturer’s duty to use reasonable care in the design and manufacture of a product to minimize injuries to its users and not to subject its users to an unreasonable risk of injury in the event of a collision or impact should be recognized by the courts.”).

55. *Id.* at 504 n.7.

Before that, you could only sue the dealer from whom you purchased the car (where you were “in privity”). Because you had no direct relationship with the manufacturer, you were limited to the express warranty that the manufacturer issued, if there was one. But you could never sue them for having been injured by the vehicle based on negligent manufacture.

So the way that the statutes are written is so important. For example, federal auto safety law preempts all state standards. So there is no role for the states at all on auto safety. But the Clean Air Act allows federal minimum standards, above which the states can issue their own higher standards. So in California you have higher standards for clean air than at the federal level. That is not permissible in auto safety, but it is as to clean air. As a result, when the California Air Resources Board would issue standards that were higher than the federal standards, then the Feds would start to come up to the California level, and the industry would come in and say, we can’t do it. And they would say: “What do you mean you can’t do it? You’re already doing it in California.” So it completely undermines their argument.

So the way the statute is written in all of these respects is incredibly important.

DAVID SWANKIN:

When you think about it, it is a really difficult decision to make—given the need for regulatory agencies to set rules to carry out laws set up for a public purpose. How do we decide how much discretion to give to the agencies? If Joan is the head of the safety agency, then I like a law that says, maybe one sentence: “The agency shall issue rules and regulations to assure safe vehicles.” But if somebody else is the head of the safety agency, I don’t like that law. When Mike Pertschuk was the head of the Federal Trade Commission, I loved the FTC section that broadly prohibits deceptive trade practices and misrepresentations and charges the agency to draw the lines.⁵⁶ But if somebody else is running the show, I don’t like that latitude. So it is not a simple answer to know how much discretion to give to the agencies.

I think what Congress and what state legislatures have often done is exemplified with the Consumer Product Safety Commission. It produced a balance: “We’re going to give you some discretion, but we’re also going to give you some limits on your discretion. You can’t set your own safety standards, you’re going to have to use the voluntary ones.” They have gone too far on that. In the field of occupational licensing by the states, most of the statutes are quite broad and they tell these agencies that they are supposed to take licenses away if “standards of practice” have been

56. 15 U.S.C. § 45 (2000).

violated. That is a very broad charge. The question is: what is a violation of the standard of practice? It has been abused. The abuses are what I concentrate on, because they are the ones that I think we have to fix.

JOAN CLAYBROOK:

We are supposed to talk about remedies in this panel.

DAVID SWANKIN:

I think we have to fix the problems like this.

JOAN CLAYBROOK:

Statutorily?

DAVID SWANKIN:

Statutorily. There is a medical board in Pennsylvania that, in the name of assuring that practice of medicine was done correctly, issued a policy statement that said nurses who operate a telephone triage line were engaging in the illegal practice of medicine. Now, we have many millions of mothers who have a hassle sending the kids off to school when the kids have sore throats and want to call somebody to find out whether they have to bring them in to see a physician to get some medicine. In the name of consumer welfare and in order to defend practice purity, you effectively foreclose most consumers from getting any medical services where needed. That is my favorite example of discretion abuse.

Now, what would you do about stopping something like that from happening? I do not think the fix is to get away from all restrictions on the regulatory agencies, because there is going to be a day when somebody is in there who is not running it the way you would like them to run it, and there is almost no way to make the agency affirmatively exercise proper discretion where given a statutory blank check. So I think we do have to agree on reasonable instructions to these agencies as they do their rulemaking to implement the will of the legislature. That is where more attention has to be paid.

At least criteria must be included so we can use the courts to enforce some floor of public protection—a check against inaction—knowing that the court check against excessive agency intervention is a given. I think finding that middle line between no instructions to the administrative agency and detailed (tie your hands behind the back) is the way we have to go.

DAVID HAWKINS:

Joan, I would like to jump back into this discussion. I think that David's principle that if Joan or Mike Pertschuk were in power, he would like them to have a lot of discretion still may work for independent commissions. I do not think it works any longer for agencies that are part of the executive branch apparatus. The problem is that all of these regulatory strangulation procedures, including executive orders to mandate analyses of cost-benefit or risk assessment, all operate according to a law of gravity that says if the agency has discretion, that discretion has to be used asymmetrically to benefit the regulated interest. I think if you analyze these rulemaking proceedings, you will come to that conclusion. So it is no longer balanced discretion. A grant of discretion in the federal regime that we are operating in gets turned into a mandate to do a lot of consideration of factors that inevitably tend to weaken the rule or prevent its issuance.

JOAN CLAYBROOK:

Actually, it is much easier for an agency head if he or she has a strong statute that says: "You should issue these rules, and do so by this date." It means you have to get funded, it means the OMB cannot stop you, and it means Congress cannot complain about it. I like strong statutes.

DAVID HAWKINS:

Right, and the remedy is to hold Congress to its promise to the people. So if you get a law enacted called the Clean Air Act, you better make sure that the rules are written under that statute so that you can hold Congress accountable for its supervening role as the promise giver. I think that is where I would draw the line. Policies have to be articulated in the law. So it says: "Base your decision on public health. If there is uncertainty, err in the direction of protecting public health." That is a policy directive. That gives us criteria that we can use in litigation when the agency ignores them.

JOAN CLAYBROOK:

Take, for example, the trucking statute that just went through a year ago.⁵⁷ One Congressman said, "I want one thing in this bill, that safety is the priority." He fought for that, and he said: "this bill is not going to go through until I get that one provision." That is a great asset.

57. Motor Carrier Safety Improvement Act of 1999, 49 U.S.C. §§ 113, 31312, 31148 (2000).

SIDNEY WOLFE:

Just extending a little bit from Joan's comments—in addition to the clarity of saying, “this federal standard shall not preempt state standards,” it also should not preempt state tort law, and we will talk a little bit about that later. Roughly sixty-three years ago, in the wake of a prescription drug tragedy that killed several hundred children and adults (elixir sulfanilamide—an early sulfa drug antibiotic), the FDA finally was given the authority in 1938 to require drug companies to test drugs to assure that they were safe before marketed. Seven years ago, under the liberal banner of Tom Harkin and the illiberal banner of Orrin Hatch, a law was passed called the Dietary Supplement Health and Education Act of 1994.⁵⁸ It strips the FDA of authority to require safety or efficacy studies on so-called dietary supplements, herbals. Just one of these products, a very popular weight-loss product called Metabolife or Herbalife, has probably killed several hundred people in this country. One of my colleagues has a son who is a third-year resident in internal medicine at Barnes-Jewish, which is the main teaching hospital at Washington University at Saint Louis. This one resident, in a period of about four months, admitted four patients to the coronary care unit. The admittees included a woman with a heart attack and another with a life-threatening arrhythmia. Both women were in otherwise good health. They had taken ephedra-containing drugs. It is natural, and natural things are good, goes the mantra. This is an example of clarity in the wrong direction. It has stripped the FDA of authority. What will happen? We talked yesterday about the crisis that has to precede lots of legislation. When enough people die from ephedra and a number of other untested (both for safety and efficacy) herbals and food supplements, then this law will be modified. Until then, it is a major step backward in FDA's authority to require companies to put out safe and effective products.

JOAN CLAYBROOK:

Why don't we move on to international trade rules. David, do you want to comment on that?

58. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified in scattered sections of 21 U.S.C. and 42 U.S.C.).

DAVID HAWKINS:

Sure. I do not practice a lot in this area, but I have a couple of comments. With the GATT (General Agreement on Tariffs and Trade) and now the WTO (World Trade Organization), we have the creation of tribunals to adjudicate disputes between countries or, more accurately, between industries in countries. The disputes concern the implicit trade barriers that may exist in a country's health, safety, or environmental laws. These adjudications have been used to rule against environmental, and other, safety rules that had been nationally adopted. For example, cleaner gasoline rules in the United States were determined to violate GATT a number of years ago. They had to be rewritten. Similar provisions relating to fishing practices have been determined to violate GATT. The problems that the environmental and labor communities have with these provisions are, first, the law of gravity that I mentioned earlier. That harmonization tends to be harmonization toward more lenient standards. Second, the process is one that does not have the safeguards that we talked about earlier in this panel; that is, we do not have a Freedom of Information Act, we do not have transparent decision making, we do not have access to the decisionmakers, we do not have the right to file comments. They do not have any obligation to consider comments or respond to them, and we do not have any remedy if they do something that we think is bad—other than try to convince our government to ignore the ruling and then suffer trade sanctions.

So there are a lot of problems with it. However, I think the idea of abolishing these institutions is not going to be a successful strategy for us. So in keeping with the theme of this meeting and taking the offensive, I would like to suggest an offensive strategy that I will label, "environmental dumping." I think that we should be looking at a long term strategy to get these international institutions to recognize this concept. By environmental dumping, I mean the existence of lenient rules in countries that export lots of products—lenient rules that harm the environment. Those lenient rules, whether it is deforestation or incredibly lax pollution requirements, are, in effect, a direct governmental subsidy to the operating expenses of those exporting industries. If they were doing it with a tax subsidy, it would be a violation of GATT—and it would be objected to as dumping. If they do it as a matter of public policy—by giving them sweetheart regulatory provisions—that should be dumping. This could be applied to child labor laws, lack of minimum wage laws, and lack of adequate working conditions as well. I think we ought to be looking at a public community effort to create the concept of dumping in these environmental and labor areas as well. I know the GATT bureaucrats will hate this and the WTO bureaucrats will hate it, but it is

a positive thing that we could start to push on. It uses their own ethic to expose their bias against future interests, and it can theoretically reverse the reduction to the lowest common denominator of market damage.

JIM HIGHTOWER:

I would go further. I think we must withdraw from the North American Free Trade Agreement (NAFTA) and withdraw from the WTO and renegotiate. Not that we should not have international rules, but these are rules that are written by and for corporate interests—period. Nobody else is at the table. You may not know it, but there has already been a meeting in Mexico to write something called the Free Trade Agreement of the Americas. It is going to be considered next month in Quebec City in Canada at a meeting of the WTO. It would extend NAFTA-like and WTO-like rules from the Arctic to the Antarctic in this hemisphere. You are not at the table, no labor interests are at the table, no consumer interests, no environmental interests, no ordinary citizen interests are at the table. Corporate executives were and are at the table writing these rules.

Now, if you go to Canada and you are a young person or you look like you might be quasi-radical in any way, you will be questioned at the border about why you are there and do you plan to come back to Quebec City in April. They want to know if you would participate in any demonstrations if you came back into Quebec City. These are the globalization rules—“globaloney,” I call it. The globalization rules are the worst thing to come our way. They are the very opposite of the rule of law. It is just raw protectionism for narrow elite interests in our world, those of investor and corporate elites. Everybody else be damned.

Not only does it override our own laws, it overrides our sovereignty. When did we vote? When did you vote? What member of Congress came to you and said: “Hey, I’ve got an idea, why don’t we take your local state and national sovereignty and turn that over to a secretive tribunal of corporate trade bureaucrats that will meet in Geneva? You cannot intervene; you can’t be a party to the process. They can meet in secret and can make their decision without even explaining it to anybody. And their decisions cannot be appealed.” Would you have voted for that? Yet, that is what we have; that is what the WTO and NAFTA are.

This is treason in my view, by the people who have voted this in. Rather than continuing it, extending it throughout the Americas,

extending it to Africa and the Caribbean and around the globe as they are trying to do, we need to stop this process. Not only is it undermining our sovereignty, but now it is also threatening our First Amendment rights in this country—as police authorities are brought in to prevent any public protest of these secretive rules.

I think this is the biggest issue to come our way in this generation. It undermines everything that we stand for as a free people, and it is being done in the name of rule writing. But you are not a part of the rule writing. Anybody who has ever been a negotiator knows that if you are not at the table, you are not a part of the deal; and we are not at the table.

JOAN CLAYBROOK:

For people in the audience who are not familiar with the WTO, it was passed by Congress as a trade agreement in 1995 in a lame duck session. It was rushed through under a procedure called “fast-track,” which means that the Congress had to vote it up or down with no amendments. The Administration, the business community, and the congressional leadership rammed it through.

The reason there is so much objection to it now (compared to the GATT before 1995) is that the old GATT said essentially that if a country gives subsidies or special import protections to its own industries, that becomes a matter for international negotiation. It was a consensus relationship. They had many debates, and sometimes countries would hurt each other by prohibiting certain products to come in or out as a result of alleged state protection or subsidy. These were called trade barriers, these subsidies and duties. The 1995 change provided that all of our health, safety, environmental, and labor rights, all of these kinds of standards that enhance our society, are now considered to be potential trade barriers.

It is true that there had been some abuse of health and safety standards. For example, in Japan there was a rule that you had to inspect every cherry. Well, that is obviously a trade barrier. But, by and large, that wasn't true. This is the most enormous corporate power grab in our lifetime, and the extension of it hasn't begun to be felt. So that is the reason that I think it is so important to look at it in relation to our health and safety standards. If a country files a complaint against any of our health, safety, environmental, labor, or other standards, then it goes to Geneva for a secret adjudication, and we can be ordered either to pay a perpetual monetary penalty or we must change our rules to eliminate that barrier.

I think that the Mexican truck issue, which you are going to hear more about, and in California probably already have heard about, is a good example under NAFTA. As Jim just described, industry was a part of

the writing of NAFTA, and they put in rules where the border had to be totally open to Mexican trucks as of January 2000. There is no nexus between the safety of Mexican trucks, which are much less safe, much older, and have no standards in Mexico at all for their safety compliance, and the opening of the border. It is a perfect example of the power of these international trade agreements.

DAVID SWANKIN:

I do not want to say anything on that issue in the interest of time, but I want to say a word about the international issue as it affects the professions and their regulation. There is a nurse shortage in this country. One of the ways some people think we can solve this problem in the short-run is to open up the doors and make it much easier for nurses trained in other countries to come to this country and practice. There is a history here where professions, lawyers perhaps leading the league in restrictions, CPAs, veterinarians, and others, have used licensing to restrict entry over the years. It has been a classic case of, “we’ll say how many and who gets into the club.” And now, at a time when there is a need, we may relax those barriers. This is all under the color of federal treaties and immigration laws. Actually, the states have the ultimate power, because their agencies give the license. They decide whether you meet their qualifications not. The record in many professions has been abusive in deciding who gets into the club. Even in times of need they are suspect. One answer is simply to make these decisions much more visible—the answer to many of these problems. This is another international problem, in addition to the trade problem.

JOAN CLAYBROOK:

Well, it is one of the incentives for the truck drivers. There is a shortage in the United States, and the companies want to hire cheap Mexican labor.

SIDNEY WOLFE:

And their big trucks to go along with it.

JOAN CLAYBROOK:

Sid?

SIDNEY WOLFE:

Just a couple of things. In the drug area, the Japanese, European, and American pharmaceutical industries formed something called the International Conference on Harmonization, and along for the ride are the governments of these three countries. It is really a series of closed meetings. Not one consumer representative has ever attended any of them. We have been invited by the FDA for briefing purposes—as more of a cosmetic. In the area of food, drug, and cosmetic law, we are worried about a race to the bottom. Harmonization means lowering our standards and possibly abrogating our own Administrative Procedure Act. We are certainly trying to be on the alert for ways FDA rules are changed—suddenly or not so suddenly—as a result of harmonization.

I was at a congressional hearing on Tuesday of this past week, and there is an international thing called the Codex Alimentarius, which has to do with food safety. The topic of the hearing was again dietary supplements, herbals, and so forth. In this case, the United States has worse standards and laws than do other countries. So the pious members of Congress said, “We don’t want this international standard setting thing to harm the sovereignty of the United States, and we will fight this at any cost.” It is interesting—if our standards are lower, the industry wants to keep them down there and doesn’t want any kind of international agreement to violate it—hypocritically and selectively defending American sovereignty.

A phrase that I think has been uttered by people in Global Trade Watch, a group that has done very effective work on global trade, is “fix it or nix it.” They mean that if it is possible to try and alter these international trade agreements and fix them, fine. Otherwise, as Jim said, just get rid of them. They are dangerous in so many ways, whether it is the environment or the workplace or elsewhere. They represent the corporations taking over the world. It can be described in no simpler terms.

JOAN CLAYBROOK:

Food is another area where the public is really going to get it on this in the not too distant future. We have already had some outbreaks and problems, but there is a tremendous move now to irradiate food, because it gives it a longer shelf life, it gets rid of bugs (things that often happen to food that is imported and hanging around for a while), and it would allow the production of much more food.

JOAN CLAYBROOK:

Produce, particularly, but imported meat as well.

SIDNEY WOLFE:

Rally your accountable California grower's industry to oppose food irradiation so that they can preserve their share of the market.

JOAN CLAYBROOK:

In fact, that is true. This is an area where local growers should really be opposed.

JOAN CLAYBROOK:

We are now going to talk about litigation, appropriations, agency administrators, the media, and constituencies; and we are going to zoom through these, because they are a little bit less complicated, and we will leave time for questions. So I hope that you will write down any of your questions and make sure they get to David Vladeck. Dave knows a lot about this topic as well, so he is a very good editor of any questions you send up.

We are going to start first with litigation and again turn first to David Hawkins, who has done a lot of agency litigation.

DAVID HAWKINS:

Litigation is one of these tools that both sides can use, but it is very important to us. If I had to vote whether I wanted to deny the tool to both sides or make it available to both sides, I would certainly vote for the latter.

We do three kinds of litigation. I mentioned one before, which is to enforce statutory deadlines for action by agencies. These are pretty cut-and-dried things, and we call them "deadline suits." Typically, what happens is that you file a complaint and then you enter into negotiations with the government and try to come up with a consent decree. Occasionally, you go before a judge because the government will not agree to a reasonable timetable for getting something done.

The second type of litigation is the judicial review of a regulation. Again, this is something that both we and the regulating industry use, and this one is a closer call as to who gets more benefit from that tool. But I still think that in an accountable government, it is very important for the public to have the right to review agency actions.

Third is direct citizen enforcement of rules issued by agencies. The EPA writes rules that apply to polluters, and while the federal government can enforce those rules, the Clean Air Act and other environmental statutes

give the rest of us the right to enforce those rules in federal district court. That is quite important, and we have used that a lot as well.

JOAN CLAYBROOK:

One of the tools that we have also used in this area is to write into the law the right of citizens to bring lawsuits. For example, in the Clean Water Act,⁵⁹ there is authority for bringing lawsuits against an agency when they have not enforced the law, and there are attorneys' fees attached to it. That ensures that the law will more likely than not be enforced, because citizen's groups, if they can get attorneys' fees, are more likely to take the risk of doing it. NRDC and some other groups—Trial West and Public Justice—have specialized in using the citizen suit provisions in order to make sure the agencies do enforce the laws.

There is a dynamic effect to litigation. The agencies know that when organizations file a petition for action and the agency ignores it, they are going to face litigation to make them accountable. In some ways, it gives the agencies backbone. It forces them to pay attention. In addition, of course, litigation is used to enforce the Freedom of Information Act. That is something that is essential, and it also allows attorney's fees. It is essential to have that litigation authority so the agencies treat citizen issues and actions seriously.

DAVID SWANKIN:

Citizen groups suing agencies to force them to do their job is critical. This is especially true as to the potential abuses of self-regulation, where you need that protection. There was an attorney general in Maryland in the mid-1980s, Steven Sax, who was one of the best ever in looking at the excesses of health and safety licensing boards. He looked at their rules and said: "Look, this rule has absolutely nothing to do with safety, it's an economic protectionist rule." He was one of the most critical attorneys general and took action against many of the cartel restrictions for business protection rather than for health and safety. He did it for optometry, dentistry, hearing aid dealers, and the funeral directors. Even though he was the attorney general of just one state, it had a national impact.

We're supposed to be concentrating on fixes. This morning we heard about public-private partnerships. I think we all ought to be able to look to the attorneys general as allies in this, because the attorneys general are an interesting phenomenon. On one hand, we have the lawyers for the boards. And as all attorneys, the boards are their clients. They are there to defend their clients. But I think they have a higher duty. The higher

59. Clean Water Act, Pub. L. No. 95-217, 62 Stat. 1155 (codified as amended in scattered sections of 33 U.S.C.).

duty is to do all of their work in the public interest. I think when the attorney general sees boards, either in their rule making or disciplinary actions, in excess, they are in a position (as a lot of private lawyers are not) to say: "You cannot do that, it is contrary to legislative intent." So I think that the public interest community and the attorneys general ought to develop an even closer relationship.

SIDNEY WOLFE:

One of the reasons why Bob and the Center for Public Interest Law have been so successful, as those of you at the banquet last night were reminded, is that they have worked in all three branches of the government. I think that litigation has to be viewed as a necessary component in overseeing regulatory agencies, in addition to legislation. David Vladeck and our litigation group have been involved in many cases. We have petitioned OSHA eight times to set standards. Most of the time they have done so, and in every single instance it had to be preceded by litigation. We have never been able to get them to set any standard without suing them. In some cases the courts have issued some fairly harsh statements about them.

In the case of the FDA, we asked the FDA to ban prescription drugs twenty-two times at last count. In thirteen of those cases, the drug has been banned and in an additional eight, severely restricted. In only several instances have we brought litigation. But to emphasize the point that Joan just made—they know that we can, so in a number of instances the filing of a petition (backed up by a lot of the data that we get through the Freedom of Information Act and now the Federal Advisory Committee Act) is extremely helpful.

So I think that litigation is a key strategy. Just as was said yesterday, one of the unmet parts of the civil rights movement is campaign finance reform. All of this fuses together in terms of the redistribution of power. And we are really all here because we believe that power is being abused, it needs to be redistributed, and litigation has to be a major component of that.

JOAN CLAYBROOK:

We will move on to appropriations, and I should have said authorization also. Agencies at the federal level are often reauthorized every three years. I know at the state level they often have sunset reviews, for example, in Texas, every twelve years. So they are

automatically required to go through a review process. And then, every year at the federal level (usually at the state level as well), appropriations committees have to allocate actual dollars to agencies for them to operate. The appropriations process, and to a lesser extent reauthorizing the agency's continued existence, has been used to curtail, and in some cases to enhance, these agencies. We certainly used the appropriations process in the 1980s and the early 1990s in the United States Congress to give assignments to these agencies to say: "You must issue a rule by this date; you must take certain actions." The business folks have copied our idea, and they started putting riders on appropriations measures that are negative, telling agencies they are not allowed to use this money to do one thing or another. We will very briefly discuss this topic. Go ahead, David.

DAVID HAWKINS:

Unfortunately, I think the appropriations process has become mostly an opportunity for the regulated community to stymie effective government action, either by starving the agencies through reduced appropriations or through riders, as Joan mentioned. Riders are specific provisions written into appropriations bills that prohibit the agency from spending money on an activity that a statute either explicitly authorizes, or indeed, in some cases that a statute commands, the agency to perform.

So it is another one of these examples where Congress has an opportunity to pretend that it has responded to the public demand for action, and then a year or two later, in a much less transparent process, undercut it by either starving the agency of resources or prohibiting the agency from doing the very thing that the members of Congress commanded the agency to do. It is very much an inside baseball operation. It is difficult to get the press to cover it, and it is also a challenge. It is a very resource intensive, detailed activity for the public interest community. It is extremely difficult for groups outside of Washington, D.C. to engage in this, even with the Internet and the Thomas Web site that gives you access to bills. A lot of the appropriations process is done at the last minute, using drafts of Appropriations Committee report language, so they never get posted onto the Internet until they have already been passed out of subcommittee or committee, and by then you are fighting uphill. So this is a challenge for us to think innovatively about a fix. I do not have a remedy to propose, just a diagnosis.

JIM HIGHTOWER:

I think this is one of the areas where the progressive community has been in exactly the wrong posture. We are on the defensive constantly

for the very reasons David just articulated. Rather, we should be on the offensive, using the appropriations process, as the other side does, to de-fund things that we think government should not be doing. For example, the fight to eliminate the funding for the “School for Americas,” known as the “School of Assassins” in Latin America, located at Fort Benning, Georgia. The fight to de-fund the building of timber roads for timber companies in our national parks, and so forth. But also, I think we could go on the offensive. I have urged this for a long time, going back to when Susan DeMarco and I wrote a book called *Hard Tomatoes, Hard Times*⁶⁰ about land grant colleges—where the money is going there. But what we urged is that consumer groups and family farm groups, organic groups, farm worker organizations, and environmental groups team up, not merely to take away the funding for the land grant colleges, but against doing research for biogenetics or whatever thing that is going to work against us. Rather, we should go to some of the researchers themselves and say, for example: “If you will develop an organic program, we will go to the state legislature on your behalf, and we will go to the county commissioners, and we will go to Congress critters in Washington, D.C., and we will try to say this is what we want to have happen and really get behind it.” Just as the other side uses the appropriation process in a negative way, we can use it in a positive way to get funding for what we want. Nothing cheers a government researcher more than saying: “We’re willing to fight for your funding if you have a positive program.”

DAVID SWANKIN:

You think it is bad, David Hawkins? Then I will tell you of a worse system—when there are no appropriations at all. In the licensing system in many states, that is the case, because the entire agency is run off of fees that the licensees pay. Take medicine as an example: the Medicare Peer Review organizations that I mentioned before, who are responsible for overseeing the Medicare population, have between five and ten times as much money as do the medical boards in most states. In California I asked the medical board what they had to go through to get a ten dollar or fifteen dollar or twenty dollar raise in the fee in order to finance themselves. Then think about professions like acupuncturists, where there may be a thousand of them licensed or eight hundred, and how

60. JIM HIGHTOWER, *HARD TOMATOES, HARD TIMES: A REPORT OF THE AGRIBUSINESS ACCOUNTABILITY PROJECT ON THE FAILURE OF AMERICA’S LAND GRANT COLLEGE COMPLEX* (1973).

much can you charge per year? And if you are funded by fees, what are you going to do when you get a really tough case that you have to prosecute, that is going to cost a lot of money? And they can cost a lot of money these days. So the notion of funding through user fees has adequacy and conflict of interest problems.

In New Jersey the medical board was asking questions on their renewal applications about chemical dependency. This is not public information; this was information that the board needed to know in order to do its job. The state medical society sued them for violating the Americans with Disabilities Act. And the Justice Department Division, bless its soul, sided with the medical society. The consumer community was supportive of the New Jersey board in this case, because we had been pushing them to get the information and they needed it. It came to the point where they lost in the district court, and it had to be appealed. They dropped it. Do you want to know the reason they dropped it? One reason: money. They could not afford to take it to the next level. Under-financed agencies at this level are intolerable for many reasons.

We have a sunset review process that is good in some states. It is not every twelve years; in some states its every four years. In some states, it is done through agencies, with some independence, similar to the General Accounting Office or the Inspector General. Some very good models exist. If we could marry good sunset review with appropriations with what Jim just said, that is what we have to do.

A final note about appropriations is that they become the oversight vehicle for these agencies. There is nothing worse than an agency that is not overseen. So I think that I will agree with all the problems of appropriations, we have to accept it's value and then try to make it work.

JOAN CLAYBROOK:

There are some proposals to have a sort of overarching federal allocation and then divide it up. I guess one of the good things about the independence of the appropriations committee in the Congress is that it would never allow that to happen, because they care about their own jurisdiction. Finally, the Budget Act has given them markers, if you would, for broad areas of funding. But the oversight function is a very important one.

SIDNEY WOLFE:

It is even worse than David just mentioned, because in a number of states, such as the one where I am licensed as a physician (the District of Columbia), the state does not even get to keep all the money that it collects in licensing fees. In the District of Columbia it goes into a sort of hole somewhere, and the four thousand of us licensed do not have one

full-time employee for the medical board.

I generally agree with the idea that government regulation is too important to be left up to user fees. In the early 1990s the Food and Drug Administration faced a false hue and cry about important drugs getting to the market here after other countries approved them. Everyone seemed to go along with a Prescription Drug User Fee Act which says that if you are a drug company and you are going to apply for a new drug application, you basically fund the Food and Drug Administration staff to review your new drug application, be it half a million dollars or more. Not surprisingly, tied in with that were implications that applicants would get special treatment if they did this, a guaranteed time for decision, and so forth. That has turned out to be a real disaster. Now there is an effort to extend user fees, not just for the review process, but for looking at safety issues that arise after approval, which would be even worse.

So I think that if we believe in government regulation, and we do, it really needs to come through the appropriations process. I remember the one time I testified in an FDA appropriations hearing there were only a couple of witnesses. One of them was Boyden Gray, former White House consultant to Bush One, who was representing a right-wing organization hoping to de-fund the FDA. And here I was, fortunately supported by Dick Durbin. Dick Durbin was on the appropriations committee for the FDA before he was elected to the Senate, and he was very vocal.

I think this makes the point that was just made. During these years when we have not been able to have real oversight hearings, at least we have fed questions (if not appearing as witnesses before Appropriations Committee hearings). They are the only form of oversight that occurs during lean years.

JOAN CLAYBROOK:

Of course, one of the problems is that now there is the five-minute rule in the Congress. That means you have got five minutes, and that is it.

SIDNEY WOLFE:

But questions could be asked, and they just haven't been.

JOAN CLAYBROOK:

Questions could be asked, that's right. Absolutely. We will now

move on to the issue of the agency administrator, the discretion the agency administrator has, and also perhaps we can comment on the oversight of the administrators themselves—the approval process through the United States Senate.

SIDNEY WOLFE:

The appointment process, right?

JOAN CLAYBROOK:

Right, the appointment and approval process.

DAVID HAWKINS:

In the interest of saving time, I only have two words to say about appointments: James Watt.

JIM HIGHTOWER:

What upsets me more than even the James Watts and the Gale Normans and the Christy Todd Whitmans is when our side wins and then we get agency administrators who don't do anything. They sit there and say: "Well, we're bound by the law, we're restricted." I have been an agency administrator, an elected one, much to the amazement of the chemical lobby in the State of Texas. As Agriculture Commissioner there, I had a lot of regulatory authority—everything from eggs to brown snails and pesticides to gas pumps we oversaw, but the pesticide authority was particularly important. I tried to practice what I think progressives should practice if they should become an agency head, whether elected or appointed: be an instigator of change; use the opportunity to the fullest.

In my first meeting with my staff, I recalled something that Franklin D. Roosevelt said when he took office in 1933 in the middle of the Depression. He said to them: "Do something. If it works, do it some more. If it doesn't work, do something else." And that was my mandate. But I also said to them: "You've got four years. Assume you have four years. I have no idea whether I can get re-elected or not, but let's act as though we have four years to get it done, and get out there and kick ass." As it turned out, we had eight years to get it done, but when we have the opportunity, we need to seize it. Progressive groups need to insist that these agency heads use the opportunity, not that they merely sit there and hold the office. We have had way too much of that in the last Democratic administration.

JOAN CLAYBROOK:

I agree with Jim on the role of the progressive agency administrator. I

think all three of us attempted to do what Jim said when we were in office. It is not easy. One of the issues that agency administrators constantly face is political challenges from the legislature. I found myself working on Capitol Hill to try to bring along the legislators to support regulation.

I will just tell one quick story. I used to see the newly elected members each time they came in, because that is when they are green and a little bit malleable. I went down to see one new member of Congress who had been a staff person on the Hill for a number of years, and then this member had retired, and he ran for that office, a guy named Coelho. I think you all might remember him. I said to him, "We've just issued an air bag standard, and we have some other controversial issues coming up." He said, "I can't really support your air bag; I'm sorry. I can support some of the things you do, but I really can't support that kind of regulation." It really sort of blew my mind. I was really irritated, and I said, "It's the auto crashes that are the major cause of death and injury and paraplegia and quadriplegia, and all sorts of different problems, including epilepsy, among a substantial part of the population." And he said, "Epilepsy?" I said, "Yes, epilepsy." And he said, "You know, I'm an epileptic." I said, "No, I didn't know you're an epileptic. When did you become an epileptic?" He said, "After I had a crash in a pickup truck when I was sixteen." So I said, "And so an air bag would have prevented you from being an epileptic." He sort of looked at me and stared at me and said, "I guess I support air bags." And he became a great force. Communication with the members of Congress, going down and talking with them and making sure that they understand the reasons why you are doing what you are doing is an extremely important function of an agency administrator.

In terms of the agency discretion, agency administrators have enormous discretion, and they have no discretion; it is sort of both. They have enormous discretion until someone decides that they want to challenge them, and then problems kick in. Because of all the procedural rules that we discussed earlier, agency administrators have less discretion than they used to. In some ways we like that, and in some ways we don't. We have talked about that a little bit. But whether they have a lot of discretion or it is reduced, an agency administrator can make all the difference in the way that agency works. The civil servants who work there have to obey the agency administrator's decisions, and that guides the whole tenor of that agency.

DAVID SWANKIN:

This is a subject that I can go on about for a long time.

JOAN CLAYBROOK:

No, no, we're not going to do that. You've got three minutes.

DAVID SWANKIN:

But it is probably the largest single flaw of regulation, the appointment process to these boards. In terms of our state regulatory boards, most, or all of the positions, are held by the regulated profession. They regulate themselves, using the power of law, which supposedly derives from the people.

The appointment process works by having governors appoint the members from the profession. We talked a little bit this morning in the Court Strategy Session about the ABA review process. Let me read you the worst one of all, from the Maryland law that governs the appointment of professional members to the Dental Board: "The Governor shall appoint the dentist Board members, with the advice of the Secretary, from a list of names submitted to the Governor jointly by the Maryland State Dental Association and the Maryland Dental Society."⁶¹

I believe the same is true for the medical board. They have to appoint the people who the private trade association recommends. Contrast that with the public members. Public members are appointed by the Governor, there are absolutely no standards. There are negative disqualifiers that are sometimes overlooked. The negative disqualifiers include the proviso that you cannot be a member of the profession or be married to a member of the profession. So we have typical examples where the public member on the Medical Board is the lawyer for the hospital association. It is incredible what we have done and what we haven't done. Actually, it is sad that the public interest community has not gotten into this issue. It's a shame.

What happens is that you have got a great law, but you get the wrong administrator, and now you get self-interested boards. Increasingly, we have won more public members on some boards—it began here in California. Public members were put on boards to make them accountable, to make them credible. That is the reason for it. If there are no standards for them—standards like a track record of public

61. MD. CODE ANN., HEALTH OCC. § 4-202(a)(3) (2000).

service, standards such as demonstrated connection to the community—so that they have some ability to tie to all of us as they sit on the board, the reform has limited value. You get the spouses of campaign contributors or people with ancillary economic interests. There are two thousand public members on state boards nationally in the health area alone. They are generally appointed by governors. In a couple of states they are selected by the legislature. Two thousand. And the public interest community, with California being the big exception, makes very little effort to get our people in these jobs, and that's too bad. So if I could change one thing, that is the thing I would change—besides ripping up that law in Maryland.

SIDNEY WOLFE:

I will take only a minute to say that under the Clinton-Gore Administration, measured in a variety of ways, the record at OSHA is the worst since the law was passed. In thirty years, it is the only Administration (and over eight years) not to put out a proposal for one single chemical health standard. Similarly, the FDA record is the poorest in the last thirty years. In the case of OSHA, the Secretary of Labor just did not really care about occupational safety and health and picked people to head the agency that just were not smart enough, gutsy enough, or progressive enough. So even when our side wins—if one is shameless enough to call the Democrats “our side”—they screwed up on these two important health and safety agencies.

They did somewhat better in the EPA, but I think David would agree that, given what could have been done in eight years, not much happened in relation to the potential. So there somehow needs to be a remedy to apply much more pressure, so that when someone gets elected or even while they are running, they make some kind of commitment to these areas. We never heard about little details, like the Food and Drug Administration, which affects a quarter of the economy of the country, or worker health and safety, raised as issues in any of the presidential debates. We need to get these people committed to these important areas. Otherwise, the important electoral process becomes foolish.

JOAN CLAYBROOK:

Let's move on quickly to media. I don't know that there is a whole lot to say about how important the media are, but we all believe they are. David?

DAVID HAWKINS:

I'm going to give my minute to Jim, who is the master.

JIM HIGHTOWER:

I was editor of the *Texas Observer* when I stepped down to run for political office in Texas, thereby making the only downward career move you can make from journalism. But obviously, the media are important, both negatively in terms of how they misreport regulatory issues, and how they fail to inform the public in advance of regulatory decisions being taken. The media are very good at saying, "Yesterday, such-and-such commission screwed you to the wall." But they are not so good at telling us it was coming ahead of time.

Now, we can wring our hands about all this, but that does no good. We ultimately have to pressure the establishment media to do a better job. But more useful is to develop alternative sources of information, and that includes groups like Public Citizen and others that do an excellent job of getting out and forewarning people of what is coming. They have the details—who to contact to do something about it. They do this not only through their publications, through their speeches, and other media but through their Web site as well: www.citizen.org. The Internet is a terrific source for all of this, and we need to find ways to extend it. Newsletters, such as mine, the *Hightower Lowdown*, do some of this as well. So does my Web site, www.jimhightower.com. But the point of all this, besides shameless hustling up here on the podium, is to say that we have got to find our way around the blockades in the media as a public interest and a progressive movement. Young folks particularly, are headed in this direction with the Independent Media Center, the Internet work that they do generally. The Media Center does a lot of streaming live on the Web, and other resources are available to us. But the establishment media basically have been a miserable failure in covering these issues. They often have conflicts of interest in terms of their conglomerate ownership. That is the reality we are faced with.

JOAN CLAYBROOK:

I would say that we should do exactly as Jim says, but I would also urge that all public interest groups try and work with the TV magazine programs. They are always hungry for information and suggestions. I have seen on many occasions where they have covered an issue, embarrassed the industry, embarrassed the agency, and have caused them to behave differently. I would certainly say in the Firestone tire

case, which I was deeply involved in, that they were definitely the reason why legislation passed upgrading the authority of the Department of Transportation's National Highway Safety Administration. The media coverage was extensive. No one can quite figure out why it happened to be in this case, perhaps because Explorers are widely used by the media? I don't know. They are expensive vehicles, and these folks know how to make a fuss. I am not sure, but whatever the reason, the media can make a huge difference in what we do.

DAVID SWANKIN:

I think much reform of state medical boards has come about because of the media—and the material that was given to the media effectively. We heard about *Code Blue*⁶² last night. *Code Blue* was responsible for California medical regulatory reform—because you got it in the media. And the most significant report that has done the most to put safety on the front page in the health field has been the Institute of Medicine's Errors Report.⁶³

Another example of effective media was on the front page of *USA Today* years ago. Do you know why it was effective? First of all, because lawyers did not write the press releases, and there was a box that said: "automobile accidents, 50,000 deaths a year; hospital deaths, 80,000." That was all it had to do, that one little chart. It was now a national issue and it stayed a national issue. I think we have to stop thinking like lawyers. These are citizen issues. I think one of the reasons you have been effective, Sid—because your stuff does get covered—is because it does not come out as a legal issue, but as a citizens' issue.

SIDNEY WOLFE:

That is because I had the disadvantage of not having gone to law school.

JOAN CLAYBROOK:

Most doctors don't know how to do it either, Sid.

62. ROBERT FELLMETH, CENTER FOR PUBLIC INTEREST LAW, A CODE BLUE EMERGENCY—PHYSICIAN DISCIPLINE IN CALIFORNIA (1992).

63. COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, INSTITUTE OF MEDICINE, TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (Linda T. Kohn et al. eds., 2000).

DAVID SWANKIN:

You just have to give it to them in a way so they'll cover it. It is our responsibility. You can bang them on the head and say, "Why don't you cover us more, why don't you cover us more," and obviously conflicts exist, but we haven't done the job, because we have been thinking like lawyers instead of like citizens.

SIDNEY WOLFE:

Just a pair of examples as to how the media message has an enormous impact on agency action. Back about ten or fifteen years ago, the drug industry managed to get out the myth that miracle drugs available in other countries were not approved here. We had a drug lag. In fact, it turned out that every single AIDS drug, for example, was approved here before it was approved in any other country. But that alleged drug lag helped to fuel some efforts to weaken the FDA.

Because of the weakening, we wound up having a number of drugs taken off the market that should never have been approved in the first place. And now, instead of a drug lag, we have sort of a log of deadly drugs. I can tell you that between the various three or four of us who worked on this issue in our group, we have been on the evening news or *Good Morning America* probably twenty, twenty-five times, just on these issues. So we have not heard for a long time about this drug lag, because in the wake of it came something that is more accurate and more interesting. I think that is very important.

I agree with Jim—there are certain areas where the media does a miserable job. In the thirty years since we started this group, there has never been any time when occupational health and safety issues have been covered. They just are not interested in those workers, in those dirty workplaces that neither we, nor they, have been in. I actually was a chemical worker once myself, so I think that helps to fuel my interest in it. So there are certain things that we just have to keep pushing. One reporter in Houston has published a number of articles on brain cancer and other problems caused by chemicals, but he is an exception. The media needs to be used. Joan is right, these low-budget magazines, including *Sixty Minutes* and others, are hungry to use our research to their own advantage. Generally, if you push hard enough, you will get a modicum of credit for it. But more important is that issues that have not gotten covered very much, if at all, on the evening news then wind up as part of the public agenda and are covered in much more depth.

JOAN CLAYBROOK:

I would certainly advise any citizen group to work with a media

expert, either to get training for your organization and your staff or to work with someone on a contract basis. Or, actually hire somebody full-time, if you can afford to do that. It makes all the difference in the world.

I would like to give a plug to a program that Bill Moyers has coming up Monday night on PBS about the chemical industry. If you all are not aware of it, it is a blockbuster of a program, and the chemical industry is berserk about it, so it must be worth watching.

An example of direct public education is a workshop on trade issues called, "FTAA for Beginners."⁶⁴ It analyzes and presents the facts on international trade issues, and it is terrific.

SIDNEY WOLFE:

Whose workshop is it?

JOAN CLAYBROOK:

United For a Fair Economy. Information is on the Web at www.ufenet.org.

The last topic that we are going to talk about is constituencies and how important they are, and we will start quickly with David.

DAVID HAWKINS:

All of us are the constituents of these health, safety, and environmental agencies. These government agencies deliver to us the products and services that we cannot buy in the marketplace, and we pay good money for them, whether we get them delivered or not. We pay it in our taxes, and we all deserve a good return on that. But we are not going to get clean air, clean water, safe workplaces, and sustainable agricultural and mining policies from the market system; the imperatives just are not there. We need to demand that we get that kind of service from these agencies—instead of succumbing to the rhetoric that “the government is them.” The government is *not* them, the government is us. Now, these agencies are important to give people what we cannot get from the private sector. And we are the constituents of these agencies. We have to both remind ourselves of that, and to remind the agency that this is what their job is—to deliver these services to us. It is not to do all the other things that the political system tries to foist upon them.

64. See United for a Fair Economy, *FTAA for Beginners Workshop*, at http://ufenet.org/econ/workshops/ftaa_for_beginners.html (last visited Feb. 1, 2003).

In terms of constituencies that help get that job done, I think the Internet is a great tool for this. We can reach out to people and make people aware of the fact that an important decision is about to be made, as Jim Hightower said. With the press, you learn about it after it happened. The Internet gives us the opportunity to tell people that a decision is about to be made, so when the Forest Service was thinking about rules to protect current roadless areas in the forest, we were able to get messages out to millions of people that this was happening. Weigh in. Use your voice. The Web is a great tool, the e-mail services are a great tool for organizing and delivering lots of messages. The plug for my organization is: www.nrdc.org. We have a lot of opportunities for citizen activism on the web, as do all the other groups. It is a tremendous tool, we just need to do more of it and do it more effectively.

JIM HIGHTOWER:

I agree. I think this is really the most important of our eight topics today—constituency power, the development of constituencies around these public interest issues. I had my own experience with this as Agricultural Commissioner in Texas, as I mentioned earlier. We came into office, and we had regulatory authority over pesticides. I thought, “what the hell, what if we actually tried to use it?”—which nobody had done previously. We put together comprehensive pesticide rules to protect farm workers and people who lived up against fields from pesticide drift. This caused quite a little brouhaha among the chemical lobby and the farm bureau in the state, who came to hand my head to me. They went to the legislature. Then they went to the governor, a Republican governor, and they came after me on two fronts: one, to make my office an appointed rather than an elected office (and I did not think they had me in mind to get the appointment), and secondly, to remove the pesticide authority from the Agricultural Department and put it in the safe waters of the Texas Natural Resource Commission. Rather than try to fight an inside fight, where I was a dead man, we went to the countryside, to political constituencies that I had, and then added to it those constituencies that do not particularly like to be poisoned.

So what we had was this: when they brought these two bills together in a hearing in the Texas House of Representatives, they had to move the hearing into the House chamber. That is how many people showed up. My lead-off witness was Willie Nelson, and my second witness was Barbara Jordan. My third witness was the Dallas Republican Women’s Organization, because it turns out that even Dallas Republicans don’t like poison on the food that they are giving to their babies. The result of this was that no member of the committee would even move to take the action that was being proposed. So they backed away. Now, if I had stayed

inside and made a legislative fight, the Texas Agricultural Commissioner would be appointed and pesticide authority would have been removed.

I can tell you that they ultimately did get me in the 1990 re-election race. But these pesticide regulations are still in place, and they are in place because there is actually a constituency for them. That is what we have got to build. Joan and I were talking yesterday, and I mentioned that when I became of political age, in the '60s, the action was in Washington, D.C. John Kennedy, "ask not what your country," and so forth. It was civil rights and the antiwar movement. The fight was in Washington. But now the action is not in Washington for our progressive future, it is in the countryside. That is where the enthusiasm and the energy is. That is where "little *d*" democrats are fighting out there, and we need to tap into that energy and build those constituencies deliberately. I think that our large progressive organizations must develop a much stronger grassroots strategy and a stronger grassroots emphasis, decamping as much as possible from Washington, D.C. I understand the need to stay and fight the defensive battles, but it is time to go on the offensive. That battle can only be won from the countryside, by rallying actual people.

JOAN CLAYBROOK:

Well, I couldn't endorse what Jim said more. I would say that there are some tactics and tools to help do that. One is something that is used in many states—public funding for participation by citizen groups in these agency decisions, which help with transportation and sometimes with research. We had some of this in the '70s in Washington—applicable to the Federal Trade Commission and the agency I headed (the National Highway Traffic Safety Administration). They were all eventually de-funded. I think we ought to go on the offense and try and get them funded again, because many citizens simply cannot participate at the right time and the right moment without that help. There is also the citizen utility board (CUB) concept, which Ralph Nader invented, that still exists in some places, such as Illinois and here in San Diego. There is a check-off card enclosed in your utility bill, and you can then form an organization without having the enormous expense of sending mailings to get them started and to continue them.

Also, we have public counsel. In New Jersey there was a public advocate that was funded by the state and was designed to be an intervenor in the state agency decisions. It was disbanded in the '80s. In the '70s we tried to get a consumer protection agency law passed. We

missed by one vote, if you can believe it. It never did pass, but while we weren't looking, they passed one for the Small Business Administration, and they have had one successfully participating for twenty years now. Then, of course, attorneys general have consumer protection offices and will often help in some of these agency proceedings at the federal, as well as the state level.

However, Jim was talking about reaching out to the public at large. There are many, many interest groups that really care about the things we do. I think more of the citizen groups are going to have to devote their resources to organizing and bringing those constituency groups together to add to the people power in our nation. That is about the only way we are going to take it back.

DAVID SWANKIN:

This is going to be short. I say "amen" to what you said and what Jim said. There is one other form of intervention that we could learn from, especially if we empower it: the long-term care ombudsman. If the long-term care ombudsman had adequate powers, it would have been another effective force for monitoring agencies. I think where we should pledge ourselves is at the top end of the appointment process. Earlier, in other Sessions, we talked about standing to sue at the back end: within the agency, either an independent internal check, or intervenor funding. Intervenor funding is the right model for agencies like the FTC. We have a variety of methods. Which works best depends on the setting.

Now, here is what I think we should pledge ourselves to: either going back through a sunset process or to appropriations review of an agency or when a new agency is created. Let's get one of those mechanisms for broad citizen participation into every single regulatory system, federal and state. Every single one of them. It is just a checklist. It is not a complete agency until you have one or more of those methods. That would give us a long-term agenda, because it would take a while to do that. But it would matter. It is not a complete process until you have an internal ombudsman or intervenor opportunity and funding or broad standing for citizen court challenges or an appointment process devoid of occupational conflicts or some or all of the above.

SIDNEY WOLFE:

The medical boards, in too many instances, are really there to protect doctors from being disciplined. That they are made up of handpicked doctors because they are not going to discipline their friends is the mechanism whereby that happens. The only purpose of the health and safety regulatory agencies is to protect the public, period. If they are not doing that, then they are not doing their job.

I would just like to mention, though, fake constituencies. With almost no exceptions that I can think of, every patient group that is disease specific in this country is funded in part by the pharmaceutical industry. And they present a constituency that often needs to be undermined as quickly as possible. If you ever want to see something amusing, go to a Web site called, www.nofreelunch.org, started by a physician friend who is head of the residency training program at Columbia. His point is that there is no such thing as a free lunch. Those patient constituencies groups think that it is possible to take money from the drug industry and not (at some conscious or unconscious level) carry the call for them. They are wrong.

There are certainly a plethora of fake constituency groups—five or six years ago, Citizens for a Sound Economy, and so forth. We need to undermine what we have to call fake constituencies. They are usually industry funded fronts.

JOAN CLAYBROOK:

I think we are ready for questions, David. I have to say that David is one of the world's great experts in this area, having worked over regulatory agencies; whenever his voice is heard they shudder.

DAVID VLADECK:

I don't know about that. One question reflects the fact that many federal agencies, at least, (because of the daunting requirements of actually getting rules out) have now resorted to nonregulatory means of enforcing the law. They do it by adopting new policy or through regulatory letters—avoiding the public hearings required for a regulation. Maybe David Hawkins can start this discussion off and talk about the policy implications of an agency engaging in that informal process.

DAVID HAWKINS:

This has happened in response to the hardening of the arteries that I mentioned at the beginning of this session. Agencies, sometimes for good reasons, want to get something done and use these underground techniques. It is also true that these techniques are used by agencies who want to get things done and know they are going to upset the public. Therein lies the danger. I think that the appropriate remedy here is not to rely more heavily on these nonregulatory techniques, but to figure out

a way to strip away the regulatory obstacle course that has been created, and that is going to require a lot of work from our community. I would just endorse what Ralph Nader said yesterday about building institutions. We need to build institutions that have an intellectual power center to support agencies and their need to function without undue obstacles. We need to get academic institutions writing about this, writing about the opportunity cost that is imposed by the current barriers, rather than having MBA after MBA churned out of Harvard and analysts churned out of the Kennedy School, who think the only responsible way to run an agency is by having this incredibly elaborate process with every consideration of every possible factor wrapped up in a great big cost-benefit analysis bow. So there are risks with this informal process, as David has pointed out. It is the second best way of getting some things done, while we are laboring under this very complicated regulatory obstacle course. But, as I say, the remedy is to get rid of the obstacle course, and then we can have the open process that all of us are entitled to.

DAVID VLADECK:

This would best be directed to Jim. Jim, you mentioned “right to know” provisions earlier in one of your talks. I would like you to explain what you see as the value of such provisions. Some have argued that they ought to substitute for more substantive regulation, and I would like your views on that as well.

JIM HIGHTOWER:

I don’t think they should be a substitute for regulation, but this ties into that constituency aspect that I still think is the most important thing. The closer you can get the power to the constituency itself, the better off we are going to be. “Right to know” is a way to do that. Not only is it an effective way to do that, it is so effective that industry tries to undo right to know. And certainly, industry seeks to prevent it from being extended. I think this, the Internet (including the streaming of the actual regulatory proceedings) and as much information as you can get and direct exposure to what is going on to the people, the better off we are going to be.

DAVID HAWKINS:

May I add one point? That piece of paper I handed out, that www.cre.com, you look at it. One of the menu items is regulation by information. They have definitely figured out that this is not something they like. That is the whole purpose of this data quality law that they snuck into the last appropriations bill, to interfere with right to know, so get on top of it.

DAVID VLADECK:

A question for Joan, again about information. David Hawkins cited the Shelby amendment to point out the asymmetry of access. That is, industry can now get access by and large to government data, but the government has a hard time getting access to industry data (except maybe in the kinds of situations Sid was talking about, where an industry must submit its data in order to get a product approved). You had to battle with the auto industry for four years. Why don't you talk for a minute about the problems that agencies have in gathering data and how that can impede effective regulatory efforts.

JOAN CLAYBROOK:

Well, as to industry data, it is subpoena power, subpoena power, subpoena power. We had subpoena power; I used it. That is how you get information. The companies have to respond. If they don't, you take them to court, and they can go to jail. So that was very effective. Also, if they lied to the government, it is a criminal penalty under 18 U.S.C. § 1001.⁶⁵ You have to be very persistent to get the Justice Department to enforce it, but an agency administrator can certainly do that.

In terms of getting benefit data, that is much more difficult. Getting that costs a lot of money. In the National Highway Traffic Safety Administration, we spent maybe \$30 to \$40 million a year trying to get benefit data, and that was not enough money. It is very hard to gather. If you want to show the reason why you are doing a regulation and to justify it and who is going to benefit from it and how many lives are going to be saved and injuries reduced, then you need to have that benefit data. So getting the benefit data is a much harder task.

The other issue is, of course, when industry submits the data, it always exaggerates the cost. So one of the things we did in the fuel economy areas was, we set up a \$10 million program to evaluate the cost data from the industry, and we identified every plant that they had for transmissions, for engines, for each different part and piece of the vehicle they claimed was going to cost money. Every time they came in with their assessment of what the cost was going to be, we could rebut it. We used our own data rather than relying totally on industry data.

65. 18 U.S.C. § 1001 (2000).

DAVID VLADECK:

Here is a question for Sid. Remarkably, the panel has collectively talked about regulation for several hours, without uttering the phrase “economic efficiency.” As we know, that has now become the touchstone of regulation in Washington, D.C. What I would like you to do, Sid, is talk for a minute about the impact this drive towards economy optimality, as the sort of litmus test of regulation, has on public health and safety.

SIDNEY WOLFE:

Well, the whole science of economic cost-benefit analysis—if you can flatter it to the point of calling it a science—is actually a mushy form of sociology. Depending on how you put the numbers into the equation, the industry can make it appear as though a regulation will or will not be worth it. A particularly suspect aspect is the value placed on human life. They devalue human lives to bar an air standard or to impose a kind of manufacturing control on a pharmaceutical company or to put out this Occupational and Safety and Health standard. I think we have to be very wary of a process controlled largely by the industry. It can come up with numbers that may look convincing, but underneath, I think they are not.

A primary purpose of the Occupational Safety and Health Act⁶⁶ was its declaration that no man or woman shall suffer impairment to their health during their working life. It does not say that if their life is not worth such-and-such amount and if the regulation costs too much, too bad, they die. The limited valuation of human life needs to be fought. It creeps into the thinking of a lot of agencies. It has been fought off to some extent, as David Hawkins mentioned, in the rejection of industry’s economic arguments for air standards—that has been fought off even by the Supreme Court. But I think the issue has to be up front. Humans are not properly measured against industry profit, as if the two concepts are easily interchangeable. This is what the issue is really about.

DAVID VLADECK:

I would like to address the last question to David Swankin. The APA says rules should be set aside only if they are arbitrarily capricious or if they are not supported by substantial evidence. However, for years courts like the D.C. Circuit engage in what it calls “hard look” judicial review—much more searching and intense than APA precedents. What impact does the availability of judicial review and the virtual

66. Occupational Safety and Health Act of 1970, Pub. L. No. 91-596, 84 Stat. 1590 (codified in scattered sections of 29 U.S.C. and 42 U.S.C.).

inevitability that a major rule will be subject to a review in court have on an agency and the regulators?

DAVID SWANKIN:

It has a major impact on every level because, in this day and age, everybody knows the rules are going to get reviewed. Earlier we talked about how much discretion should be given to an agency and what the relation should be between the legislature that enacts the law and the agency that administers it and then the court that may review it. I think that where we came through this process was that the legislators who write good laws ought to put the criteria for setting these rules and standards right into the law. Then you have something measurable. I think that the process absolutely needs to have the check and balance of court review. They use it, and so do we. It is a wonderful protection.

So I think that it does have an impact, and I think that there is a bigger flaw on the front end than on the review end. I think the flaw is that you get poor review where the standards are not as clear and as good as they ought to be, so that you have left much too much discretion to the reviewing court. I think if we fix that front end, the review process would work better for us.

While I am here, let me say one other thing about using regulation versus cases to make precedent. The regulation route can be problematic. For example, take the Federal Trade Commission when Pertschuk implemented more aggressive regulation. The Congress imposed its required approval of FTC rules, and some issued a threat to shut it down. Because there was an allegation that they excessively used rulemaking, the agency largely abandoned rulemaking. For twenty years, they have been away from it. Now the pendulum has gone the entire other way; it is all the case method; individual cases as precedents.

Any good agency uses a mix of cases and rules. It needs the option to do it by a case decision and by regulation. If you take one away, you have tied an agency's hands irrationally. I think we are at that point. We have overburdened our rulemaking, and then we have so many overlays on top of it. I was talking to David about this at the break. We have OMB review at the federal level, and then we have court review—there is too much of it. I, for one, would get rid of OMB review. Let it go straight to the courts. That is what they are for.

JOAN CLAYBROOK:

As a summary conclusion, I would say that our regulatory agencies today are themselves the most regulated element in our society.

I want to thank the panel very much for their contributions. I don't think we need a closing statement, we all had an awful lot of time and things to say, and, I, for one, deeply appreciate the opportunity to be here.