

ADMINISTRATIVE & REGULATORY LAW NEWS



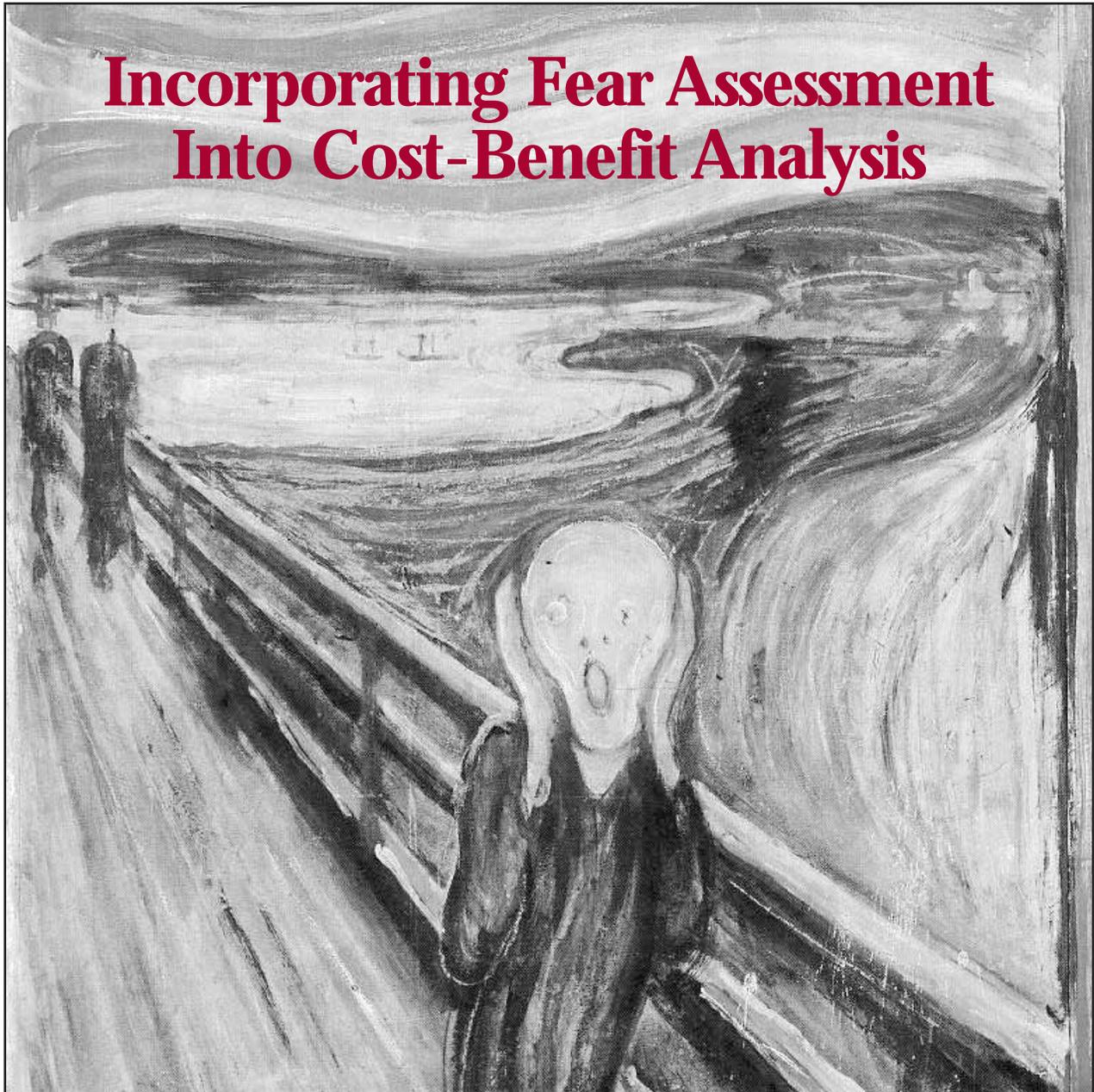
Section of Administrative Law & Regulatory Practice

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Incorporating Fear Assessment Into Cost-Benefit Analysis



Also In This Issue

- Internal Review Boards and Human Subject Research
- OMB's Revised Peer Review Bulletin
- Mead and Tax Law

Chair's Message



William Funk

This is the last *News* during my tenure as Chair of the Section. The year has at times passed swiftly and at other times at a glacial pace. What the Section has accomplished in the past year reflects on the large number of people involved in the various activities of the Section and on the leadership over a number of years.

The APA Project begun in 1998 under then-Chair Ron Cass, and which has been marked by significant achievements – the Blackletter Statement of Federal Administrative Law first published in 2002 under then-Chair Ron Levin and reprinted this year, and the Guide to Federal Agency Adjudication published in 2003 under then-Chair Neil Eisner – continues. Publication of the Guide to Federal Agency Rulemaking, 4th ed., and the Guide to Judicial and Political Review of Federal Agency Action should both be published this year. In addition, for over a year, the Section has been fine-tuning its draft proposed amendments to the Administrative Procedure Act regarding adjudication. They are now to the point that they are ready for circulation to agencies and others for comments. Council Member Michael Asimow has been spearheading this initiative.

The European Union Project, to create a statement of European Union administrative law, the brainchild of former Chair Boyden Gray, began last year and finished its first phase this February with a final report to the Council at the Midyear Meeting outlining how such a statement could be created. This project, which has received support from the International Law Section, the Antitrust Law Section, and the Section of Environment, Energy, and Resources, has been led by Professor George Bermann of Columbia Law School under the supervision of former Chair Neil Eisner on behalf of the Section. In February the Council approved going forward with fundraising activities to fund the implementation stage. Just recently the Council has again voted its support of the Project by authorizing the expenditure of funds to start the program in earnest. Professor Bermann has recruited a most impressive group of scholars and practitioners from both sides of the Atlantic to gather, synthesize, and report on a body of administrative law that lacks any central organizing statute like our APA. Already we have a number of institutions, again on both sides of the Atlantic eager to publicize our results in conferences, and we thank firms such as Wilmer, Cutler & Pickering and Ropes & Gray for their support of the project.

These multiyear projects involving many members of our Section are major undertakings, but we also deal on the more immediate level of commenting on federal legislation and agency initiatives. For example, our Section wrote to the House Judiciary Committee on behalf of the entire ABA to express our concerns about H.R. 338, the “Federal Agency Protection of Privacy Act of 2004,” and recently, again on behalf of the entire ABA, we wrote to the Subcommittee on Commercial and Administrative Law of the House Judiciary Committee supporting the reauthorization and refunding of the Administrative Conference of the United States. In both cases, alert Section members brought these pieces of proposed legislation to our attention, enabling us and the ABA to play a role in the democratic process.

We have also commented to the Office of Management and Budget on its continuing efforts to adopt guidelines for federal agencies in the use of peer review of influential scientific information. Last December we commented on behalf of the entire ABA to raise certain concerns with OMB’s draft bulletin. In April, OMB issued a revised bulletin, with changes consistent with our comments, and Dr. John Graham, the head of the Office of Information and Regulatory Affairs, personally called to thank us for our comments. Thus emboldened, we submitted further comments to OMB on the revised bulletin, this time solely on behalf of the Section. All of these comments have involved a number of Section members, including all the members of the Council, whose ideas and suggestions have, if not perfected, at least improved our final products.

As this issue goes to press, we are still working on a proposed report and recommendation for the House of Delegates supporting the use of administrative penalties as part of a comprehensive regulatory enforcement program and supporting an opportunity for formal adjudication by those subject to such penalties. This initiative came up through two separate committees, was worked on by a number of Section members, and has been considered by the Council on more than one occasion.

And none of the above reflects the fine work that is being done by a number of our committees on their own – brown bag lunches, CLE programs, etc.

My point, as well as trying to indicate some of the things we have accomplished in the past year, is that all of this activity is collaborative. Those who want to participate are

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ADMINISTRATIVE & REGULATORY LAW NEWS

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The Administrative & Regulatory Law News welcomes a diversity of viewpoints. From time to time, the editors may publish articles on controversial issues. The views expressed in articles and other items appearing in this publication are those of the authors and do not necessarily represent the position of the American Bar Association, the Section of Administrative Law & Regulatory Practice, or the editors. The editors reserve the right to accept or reject manuscripts, and to suggest changes for the author's approval, based on their editorial judgment.

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Nominations



Section Chair (automatic succession per bylaws): **Randolph J. May.** Randy is Senior Fellow and Director of Communications Policy Studies at the Progress and Freedom Foundation in Washington, D.C. He has been a Council member, as well as chair of the Section's Publication Committee and the Ratemaking Committee.



Section Chair-Elect (automatic succession per bylaws) **Eleanor D. Kinney.** Eleanor is the Samuel R. Rosen Professor of Law and Co-director of the Center for Law and Health at Indiana University School of Law in Indianapolis. She has been a Council member as well as chair of the Section's Health and Human Services Committee. She also has chaired the Publications Committee, and her book on Medicare coverage disputes is the most recent addition to the Section's publications program.



Section Vice Chair: **Daniel Troy.** Dan is Chief Counsel for the Food and Drug Administration. He is co-chair of the Constitutional Law and Separation of Powers Committee and a past chair of the Meetings Committee and a past vice chair of the Communications Committee.

Secretary (renomination of incumbent): **Jonathan J. Rusch.** Jonathan is Special Counsel for Fraud Prevention at the Department of Justice. In addition to serving as Secretary, he has been a Council member and chair or co-chair of several Section committees, including Antitrust, Criminal Process, and Regulatory Initiatives.

Budget Officer (renomination of incumbent): **Daniel Cohen.** Dan is Chief Counsel for Regulation at the U.S. Department of Commerce. In addition to serving as Assistant Budget Officer, Dan has been chair of the Rulemaking Committee.

Council Members (each to serve three-year terms):
Wendy E. Wagner. Wendy is a professor at the University of

Texas School of Law. She is co-chair of the Environmental and Natural Resources Regulation Committee.

Ronald L. Smith. Ron is Chief Appellate Counsel at Disabled American Veterans and serves as co-chair of the Veterans Affairs Committee.

Kathleen Kunzer. Katy is Senior Director, International Affairs, American Chemistry Council, co-chair of the International Law Committee and vice-chair of the Rulemaking Committee.

Bernard W. Bell. Bernard is a professor at Rutgers University Law School. He serves as co-chair of the Constitutional Law and Separation of Powers Committee and vice-chair of the Legislative Process and Lobbying Committee.

Alan C. Raul, partner at Sidley Austin Brown & Wood, and vice chair of the Government Information and Right to Privacy Committee, was appointed at the Spring Meeting to fill the unexpired term of Anne Dewey-Balzhiser.

Pursuant to the Section's bylaws and with the consent of the Council, Chair-Elect Randolph May has appointed the following persons to one year terms as ex officio members of the Council as liaisons to and representatives of the three branches of the federal government and the State Administrative Law and Administrative Law Judiciary constituencies:

Executive Branch, Jennifer Newstead, General Counsel, Office of Management and Budget

Legislative Branch, Consuela Washington, Senior Minority Counsel, House Energy and Commerce Committee

Judicial Branch, A. Raymond Randolph, Judge, U.S. Court of Appeals for the D.C. Circuit

Administrative Judiciary, Ann Young, Administrative Judge, Nuclear Regulatory Commission

State Administrative Law, Paul Afonso, Chairman, Massachusetts Department of Telecommunications and Energy

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CLE HOURS?**

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Essay

By William S. Morrow, Jr.¹

I did not vote for Ronald Reagan. Twice. But even this Doubting Thomas must admit that the Reagan presidency marks a positive inflection point in the trend line of administrative law and regulatory policy.

When asked why he was running for the California governorship in the late 1960s, Ronald Reagan replied that it was time to put an end to “administrative edict and rule.” Later, during his inaugural address following the 1980 election, he said: “Government is not the solution to our problem. Government *is* the problem.” He believed that a big businessman was what a small businessman would be “if only the government would get out of the way and leave him alone.”

It may seem now that the Reagan Revolution was a natural reaction to the “stagflation” – double-digit inflation and chronic high unemployment – that hobbled our nation in the 1970s, but his hostility for what he termed “irrational and senseless regulations” stands in stark contrast to nearly one hundred years of increasing and popularly accepted governmental intervention in private commercial relations, even if his specific regulatory reforms were not all that radically different from the deregulation efforts begun under Presidents Ford and Carter. To put this in perspective, a little history is in order.

After the Articles of Confederation and its tolerance of tariffs and other trade barriers among the States was cast aside in 1787 in favor of a Constitution more conducive to interstate and foreign commerce, it took some 100 years before the semblance of a national economy – dominated by a relatively small number of large firms – had fully emerged. The railroad industry was among the most visible and critical components, but public dissatisfaction with rail rates and practices and the Supreme Court’s decision in *Wabash, St. L. & P.R. Co. v. Illinois*, 118 U.S. 557 (1886), striking down state regulation of interstate rail operations led to the formation of the Interstate Commerce Commission (ICC) in 1887. Three years later, the Sherman Act and its

twin prohibitions against monopolies and restraint of trade came into being by a vote of 51-1 in the Senate and 242-0 in the House. Thus it is fair to say that as the 20th century approached, the public and an overwhelming majority of elected officials viewed federal regulation as an indispensable ingredient to the proper functioning of markets transcending state boundaries – at least to the extent those markets were colored by a concentration of power in the hands of a few private actors.

Despite the broad acceptance of government oversight as a legitimate and necessary institution, the government’s ability to affect private markets at first was quite weak. The Supreme Court’s decision in *United States v. E. C. Knight Co.*, 156 U.S. 1 (1895), narrowly construed interstate commerce to exclude manufacturing activities, constraining application of the Sherman Act principally to combinations and restraints relating to interstate transportation, and the ICC initially lacked any real enforcement power. The federal government’s influence began gaining traction, however, under Teddy Roosevelt in the early 1900s.

Roosevelt signed the Hepburn Act into law in 1906, empowering the ICC to determine the just and reasonable rate for rail service on the complaint of a shipper, forbidding free rail passes and expanding the ICC’s jurisdiction to include oil pipelines, bridges, ferries and terminals. This followed the 1903 Elkins Act’s outlawing of discriminatory shipper rebates. Roosevelt also took on the “beef trust” in 1906 by signing the Meat Inspection Act and the Pure Food and Drug Act. The former authorized the Secretary of Agriculture to inspect packing plants and condemn tainted meat. The latter, among other things, established the Food and Drug Administration to enforce the Act’s prohibitions against the adulteration and mislabeling of food and pharmaceuticals crossing state lines.

The Mann-Elkins Act of 1910 added communications – telephone, telegraph, cable, wireless – to the list of ICC-regu-

lated industries and shifted the burden of proof in rate cases to the railroads.

Woodrow Wilson’s anti-monopoly “New Freedom” program resulted in several incremental expansions of federal power during the teens, including: the Federal Reserve Act in 1913, (establishing the Federal Reserve Board, in part to supervise the banking industry); the Clayton Act in 1914, (banning specific anticompetitive practices); the Federal Trade Commission (FTC) Act of 1914 (technically part of the Clayton Act), (prohibiting unfair methods of competition); and the Adamson Act of 1916, (imposing the 8-hour workday on the railroad industry).

The 1920s were no exception to the trend. The Transportation Act of 1920 subjected rail mergers and acquisitions to ICC approval and installed the agency as the final arbiter of rates, routes and service; the Federal Water Power Act of 1920 established the Federal Power Commission (FPC) to license hydroelectric projects; the Railway Labor Act of 1926 required railroads to bargain with labor unions; and the Radio Act of 1927 created the Federal Radio Commission to license broadcasters.

Turning to the 1930s, it is familiar learning that the dual cataclysms of stock market crash and banking collapse in the late 20s and early 30s served as catalyst to the reform prong of Franklin Roosevelt’s “relief, recovery and reform” New Deal. Price discrimination was made illegal by the Robinson-Patman Act of 1936. New agencies came into being, such as the Securities Exchange Commission, the Federal Deposit Insurance Corporation, the Federal Communications Commission, the National Labor Relations Board, and the Civil Aeronautics Authority, later split by Roosevelt into the Civil Aeronautics Administration (CAA) and the Civil Aeronautics Board (CAB). Existing agencies saw their mandates enlarged, with trucks, buses, barges and freight forwarders added to the ICC’s jurisdiction; consumer protection duties bestowed on the FTC; cosmetics and

¹Editor in Chief

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Fear Assessment: Cost-Benefit Analysis and the Pricing of Fear and Anxiety

By Matthew D. Adler¹

Cost-benefit analysis (“CBA”) has become standard practice at EPA, OSHA, FDA, CPSC, NHTSA, and other environmental, health and safety agencies. These agencies are required or permitted by some (although certainly not all) of the statutes they administer to employ CBA in making regulatory choices. Executive Order 12,866 generally instructs regulatory agencies in the Executive Branch to conform to a cost-benefit criterion, where statutorily permitted, and to prepare formal cost-benefit documents, for review by OMB, in the case of sufficiently “significant” rules.

What, exactly, is CBA? Economists tend to link CBA to a technical notion known as “Kaldor-Hicks efficiency.” I believe that this linkage is mistaken, and have argued to that effect (along with Professor Eric Posner) in a number of articles.² Rather, Posner and I suggest, CBA is best understood as a rough-and-ready guide to *overall well-being* in deciding whether to promulgate regulatory measures, agencies – including environmental, health and safety agencies – should consider whether the gains in well-being to those individuals who benefit from the measures are large enough to outweigh the losses to those

who are made worse off. Overall well-being is surely not the only normative consideration relevant to regulatory decision, but it is one such consideration, and one that agencies ought to take account of – with the crucial caveat, of course, that a focus on overall well-being must be legally permissible. CBA, in turn, is a practicable tool for assessing whether regulatory measures increase or decrease overall well-being.

CBA, ideally, involves three steps. The “costs” and “benefits” of a given regulatory choice – the effects of that choice on human well-being – should first be identified, then quantified, and finally measured in dollars. These “costs” and “benefits” may include pecuniary losses and gains, but can encompass many other kinds of welfare impacts as well. For example, if EPA is undertaking a full CBA of some regulation imposing more stringent controls on a pollutant, it will surely seek to determine the compliance costs of the regulation. These compliance costs translate into pecuniary losses for the firms subject to the regulation, the workers employed at those firms, and the consumers who purchase products from the firms. But it has also become standard practice, at EPA and some other agencies, to quantify and monetize the effects of regulatory choice on human mortality and morbidity. So EPA will probably conduct a “risk assessment” of the anti-pollution regulation. Lower levels of the pollutant will mean fewer premature deaths and fewer cases of certain diseases. Risk assessors at the agency will try to estimate the number of premature deaths and disease cases avoided by the anti-pollution regulation, and the EPA’s CBA will translate those mortality and morbidity numbers into dollar figures so as to make them commensurable with the compliance costs of the regulation. This may seem extraordinary to those unfamiliar with CBA, but it has become

quite routine for agencies to place a price tag on life-saving (a typical valuation would be \$5 or \$6 million per premature death avoided) as well as disease-avoidance.

Finally, EPA might go beyond the pecuniary and physical (death and disease) effects of the regulation, and consider less tangible costs and benefits. There is now a large, scholarly literature in applied economics that attempts to determine the monetary valuation of a variety of environmental amenities such as the enjoyment experienced by visitors to parks or other protected areas, the recreational benefits of hunting and fishing, the improved visibility that accompanies better air quality, smell- or noise-avoidance, the “scenic” benefit of viewing a nice landscape, and the sheer satisfaction of knowing that a site, ecosystem, or species exists. Literally hundreds if not thousands of so-called “contingent valuation” or “revealed preference” studies exist in the academic literature, seeking to measure these sorts of environmental benefits on a money scale. (“Contingent valuation” is an interview-based technique for monetizing welfare costs and benefits. Respondents are asked how much they would be willing to pay in dollars to secure a given benefit, or willing to accept in return for a given loss. “Revealed preference” studies seek to infer individual monetary valuations by looking to actual behavior or market data – for example, the effect on housing prices of vistas and eyesores, or the travel costs that park visitors are willing to incur.) And EPA, in its actual cost-benefit practice, has taken account of these less tangible environmental costs and benefits, as well as pecuniary, mortality, and morbidity effects.

My suggestion is that environmental, health and safety agencies should also (at least sometimes) count fear and anxiety as a cost for purposes of CBA. EPA,

¹ Professor of Law, University of Pennsylvania Law School. This is a condensed version of a more comprehensive piece titled, *Can Fear be Priced? Cost-Benefit Analysis and the Monetization of Fear*, *CHI.-KENT L. REV.* __ (2004).

² Matthew D. Adler & Eric A. Posner, *Rethinking Cost-Benefit Analysis*, 109 *YALE L. J.* 165 (1999); Matthew D. Adler & Eric A. Posner, *Implementing Cost-Benefit Analysis when Preferences are Distorted*, in *Cost-Benefit Analysis: Legal, Economic and Philosophical Perspectives* 269 (Matthew D. Adler & Eric A. Posner eds., 2001); Matthew D. Adler, *Beyond Efficiency and Procedure: A Welfare Theory of Regulation*, 28 *FLA. STATE U. L. REV.* 241 (2000); Matthew Adler, *Incommensurability and Cost-Benefit Analysis*, 146 *U. PA. L. REV.* 1371 (1998).

OSHA, CPSC, OSHA, and FDA should engage in *fear assessment*, just as they now engage in risk assessment. Risk assessment means quantifying the effect of agency choice on death, illness, and injury and – if the agency is doing CBA – converting those numbers to monetary values. By analogy, *fear assessment* would mean predicting the effect of regulatory measures in abating (or increasing) the fear and anxiety states that various members of the population experience, and then placing a price tag on this psychological impact.

CBA, again, is a tool for determining whether a regulatory choice increases or reduces overall well-being. A full CBA should therefore identify, quantify, and monetize *all* of the ways in which a regulation would affect human welfare, including its fear/anxiety effects – with the important caveat, to be considered in a moment, that CBA itself can be costly and that these “deliberation costs” may justify limiting its scope.

Why not fear assessment? After all, fear and anxiety is a genuine cost: a genuine setback to human well-being. The cost, here, is psychic rather than physical – suffering an unpleasant mental state rather than losing a limb or losing your life. But psychic changes can genuinely constitute a change in welfare. Philosophers like Jeremy Bentham and J.S. Mill argued that human well-being is solely a matter of mental states, “pains” and “pleasures.” This view is too extreme, I think, but surely it is the case that psychological distress – fear and anxiety – is one kind of welfare cost. Indeed, the law has long recognized this in areas other than regulatory practice: for example, in the ancient tort of assault; in the more modern emotional-distress torts (epitomized by intentional fear-infliction, although unlike assault not limited to fear-infliction), and in the compensability of fear as a component of pain and suffering damages. And there is plenty of evidence that some (if not all) of the hazards regulated by environmental, health and safety agencies are the target of substantial fear. Consider the popular fear of toxic waste dumps (epito-

mized by Love Canal), of carcinogenic food additives (for example, the Alar scare), of cancer more generally, of genetically modified food, of all things nuclear (reactors, waste, irradiated substances) and, recently, of mad cows.

In fact, agencies do occasionally price fear, anxiety, or other sorts of psychological distress. The FDA last year proposed a rule that would reduce the allowable defect rate in medical gloves. The agency reasoned that fewer defective gloves would mean fewer cases in which medical personnel come into contact with human blood. Such blood-contact incidents have a variety of costs: they can cause blood-borne diseases such as HIV or hepatitis; they can lead medical personnel to order blood-screening tests, which are expensive; and the incidents can cause fear and anxiety in the exposed workers. The FDA quantified and monetized *all* of these costs, estimating that the proposed rule would prevent 100,000 blood-contact incidents annually and that the fear/anxiety cost of each incident was \$13.

FDA’s recent attempt to measure and price the fear-reduction benefit of safer medical gloves is an excellent example of regulatory fear assessment. It is also very unusual. The AEI-Brookings Joint Center maintains a database of 48 “significant” rules, issued between 1996 and 1999, where agencies prepared full cost-benefit documents for OMB review. In 13 of the 48 rulemakings, the agencies explicitly quantified and monetized death, illness, or injury. In 7 other rulemakings, the agencies explicitly quantified without monetizing mortality or morbidity effects. But there is only a single rulemaking in the database where an agency provided quantitative estimates, or monetary valuations, of fear, anxiety, or other forms of psychological distress. Perhaps even more surprisingly, although the academic literature is full of studies attempting to value morbidity, mortality, and environmental amenities, only a few academic economists have sought to estimate the cost of fear.

Why? Is there a principled reason for agencies to eschew fear assessment? I think not. There may be an historical reason why they do. The rise of risk

assessment in the federal government, and the concomitant pricing of life and morbidity by regulatory agencies, is due in no small part to a seminal 1980 decision by the Supreme Court, the “Benzene” case (*Industrial Union Dep’t v. American Petroleum Institute*³), which demanded that OSHA quantify health benefits before regulating workplace toxins. A few years after this decision, in *Metropolitan Edison v. People Against Nuclear Energy*,⁴ the Court rejected a claim by a group of Harrisburg residents, living near the Three Mile Island nuclear plant, that the Nuclear Regulatory Commission was required to file an environmental impact statement addressing the psychological effects of restarting the plant. The Court held that psychological distress was not, without more, the kind of environmental impact that would trigger NEPA (the National Environmental Policy Act). Just as *Industrial Union* fueled risk assessment, *Metropolitan Edison* dampened fear assessment – or so a plausible historical explanation for current cost-benefit practices might go. But this is an explanation, not a justification. There is no good reason, I suggest, for environmental, health and safety agencies undertaking CBA to generally ignore fear and anxiety effects.

One objection to fear assessment concerns quantification. “Fear just can’t be measured.” But in fact there are various fear/anxiety scales regularly employed by psychiatrists and experimental psychologists, such as the Spielberg State-Trait Anxiety Inventory, the Hamilton Anxiety Rating Scale, the Beck Anxiety Inventory, and the Covi Anxiety Scale; and also a small academic literature where such scales have been employed to measure the effect of waste dumps, toxic and radioactive accidents, air pollution, and workplace asbestos in producing fear and anxiety among individuals aware of these hazards. Another objection to fear assessment involves uncertainty. How can we know for certain how many states of anxiety or fear will be caused by a hazard, how intense these states will be, how long they will last? But uncertainty is a pervasive feature of regulatory choice. Consider that risk assessors never

³ 448 U.S. 607 (1980).

⁴ 460 U.S. 766 (1983).

know for certain how many deaths or illnesses will be avoided by hazard mitigation and what the compliance costs of mitigation will be. Well-developed, generic techniques for handling uncertainty about costs and benefits currently exist; these could readily be extended to fear assessment.

A third objection is that fear and anxiety, particularly the popular “dread” of certain environmental, health, or safety hazards, is irrational. Yet irrational fears, no less than rational fears, constitute genuine welfare setbacks. Consider two hypothetical individuals, Jim and June. Jim is irrationally certain that his chance of dying on a bumpy airplane ride is 1 in 100, and is quite distressed during the 6 hour ride. June rationally believes that the chance of dying from a blood-borne illness, with which she has just been diagnosed, is 1 in 100, and like Jim is quite distressed for the 6 hours until she learns that the diagnosis was erroneous. Fear, technically, is an unpleasant affective state – a bad sensation or “feeling” – caused by the subject’s belief that he or she is at substantial risk of physical harm. In Jim’s case, the belief is unwarranted; in June’s case, the belief is warranted. But in *both* cases the individuals incur a real affective cost.

It is sometimes said that communication and education, rather than direct regulation of feared hazards, is the most cost-effective way to mitigate fears. This is an open, empirical question – some fears are resistant to education – but in any event the communication/education point does not undercut fear assessment. Rather, it suggests that where fear is at issue regulators should consider a wider array of possible regulatory measures, including informational and educational measures, as well as direct prescription. If an informational measure truly is the best “technology” for fear-reduction, in some regulatory context, then a well-conducted CBA (incorporating fear assessment as a component) will select that measure as the optimal one.

A more important worry about fear assessment, I believe, concerns deliberation costs. The very process of CBA is costly. The causal linkage between hazards and various kinds of welfare impacts will need to be estimated.

Predictive models will need to be developed, and uncertainty about the models or model parameters will need to be handled. Money valuations for the impacts will need to be determined, either by searching the existing literature or by undertaking new valuation studies. Policy staff at the agency will need to review the analysis, as may external monitors such as OMB or congressional committees. Is all this analytic effort worth the benefit (the benefit in better regulatory choices) when it comes to fear and anxiety? Not necessarily. In general, the deliberation costs of full-blown CBA are not always justified, even for standard costs such as compliance costs or mortality. Executive Order 12,866 requires full-blown analysis only for certain “significant” rules, which as defined by the Order are only a small fraction of the rules that agencies promulgate. On the other hand, the benefits of full-blown analysis sometimes *do* outweigh the deliberation costs – and that is true for fear and anxiety, just as it is true for other categories of welfare setbacks and improvements. Rough threshold guidelines for when agencies should perform fear assessment could readily be developed. These guidelines might look to, *inter alia*, the size of the population exposed to the hazard; whether the population is particularly resistant to fear (for example, workers who self-select into high-risk occupations); whether the hazard is generically “dreaded,” as is nuclear power; and whether the particular hazard has become salient to the exposed population, for example because of media attention.

Finally, it might be objected that fear assessment is self-defeating in the long run. If agencies incorporate fear-reduction benefits in CBA, fear entrepreneurs will have an added incentive to make citizens fearful of the hazards that the entrepreneurs want eliminated. This objection would be quite serious, I think, if agency decisions were insulated from legislative control, or if legislative decisions were themselves driven by CBA. Imagine a technocratic world in which both Congress and agencies conscientiously resist popular pressure and use CBA to reach their choices; in such a

world, shifting from traditional CBA to a CBA that incorporates fear assessment could well end up, perversely, causing a greater amount of fear. For now, however, fear entrepreneurs have a large incentive to incite fear, regardless of the details of agency CBA, since agency decisions can always be reversed by legislators who are (predictably) sensitive to popular fears. Consider that fear-mongering is already a familiar part of the politics of environmental, health, and safety regulation even though agencies, with a very few exceptions, do not currently quantify and monetize fear.

How, exactly, should fear and anxiety be measured? And how should the measurement be converted to a dollar value? These are technical problems, best engaged by applied economists. My tentative suggestion is that agencies engaged in fear assessment might use *fear-days* as their basic unit. A “fear day” is a day during which the individual is substantially more fearful or anxious than population norms. This is just the kind of unit now regularly employed by agencies and economists for CBA of acute physical morbidities such as headaches, angina, congestion, cough, sneeze, nausea, or eye irritation. Monetary prices are assigned to headache-days, angina-days, congestion-days, etc. For a given regulatory intervention, the fear assessor might (1) estimate the number of fear-days avoided by the intervention, relative to the status quo; and then (2) price each avoided fear-day at a standard price. For technical reasons, a price per fear-day is best estimated (I think) using “contingent valuation” rather than “revealed preference” techniques. Applied economists, these days, wouldn’t think twice about conducting interviews where subjects are asked for their willingness-to-pay to avoid a bad headache, a stuffy nose, the loss of an ecosystem, an ugly view, or an incremental risk of death. Interviews focusing on willingness-to-pay not to be afraid pose no greater conceptual or practical difficulties. Another possibility is using interviews to measure fear or anxiety on a QALY scale – a welfare scale used by health economists – and then converting the results to dollars with a standard conversion factor.

My view of fear assessment makes it a separate component of CBA. Fear states need to be separately predicted and priced. Some scholars have advanced a different proposal: that fear costs be incorporated in CBA by attaching a fear premium to particularly dreaded deaths. For example, regulatory agencies might ascribe \$6 million to each premature death in a car crash or industrial accident, but \$12 million to cancer deaths, given that cancer is especially feared. The trouble with this proposal is that it assumes a tight correlation between death-reduction and fear-reduction. Imagine that by promulgating increasingly stringent measures an agency can prevent an increasing number of cancer deaths: 10 with the least stringent measure, 20 with a more stringent one, 30 with the most stringent one. There is

absolutely no reason to assume that the aggregate fear-days avoided by the second and third measures will be, respectively, twice and three times the aggregate fear-days avoided by the first measure. Fear correlates with perceived risk, not actual risk, and only then in a very rough, non-linear way. Banning a food additive or closing down a waste dump entirely might well have a dramatic effect in reducing fear but a much less dramatic effect in reducing death, as compared to the status quo and less stringent regulatory alternatives, since it may well be the sheer existence of the hazard that accounts for most of the fears about it.

I have argued here for the pricing of fear and anxiety by environmental, health and safety agencies since these are governmental bodies that are generally

conversant with CBA and since popular fears and anxieties are substantially affected by their choices. Unfortunately, in this post-9/11 world, EPA, OSHA, FDA, and NHSTA aren't the only federal agencies fighting terror. The war against terrorism is, of course, mainly a war against the physical violence that terrorists seek to wreak, but is also a war against the anticipatory and resultant fear flowing from this violence. I cannot address the matter at length here, but believe that CBA should in some contexts be employed by the Department of Defense, the Department of Homeland Security, and other national security bodies. If so, CBA by these agencies should also (with due sensitivity to deliberation costs) include a fear assessment. ○

Chair's Message

continued from inside front cover

encouraged to do so, and their input is welcomed. We always will have lots to do.

Not all is sweetness and light, however. The larger ABA is facing significant financial difficulties, and it is not surprising that the Section is impacted by these difficulties as the ABA's demands on sections increases. Unfortunately, these demands come at a bad time for us, because we have our own financial difficulties, largely as a result of the larger ABA's failure to bill more than a thou-

sand of our members, a failure that it took some time for us to discover because of the larger ABA's inadequate accounting system. At least now we are aware of the problem, even if the ABA has not yet fixed the problem, and we can budget for it. But for the short-term our belt must be kept tight.

Nevertheless, as I hand over the Chair to Randy May, I know that the Section is in good hands. Randy oversaw the most successful Fall Conference ever this past

fall, and I don't think he will let this Fall's be any less successful.

But before I disappear to spend a year on sabbatical in Germany, we still have the Annual Meeting in Atlanta. There will be programs, social activities, and important matters before the Council. I hope to see familiar faces and get to meet new attendees.

Finally, I want to thank all of those who have helped to make this a successful year. ○



Developments in Administrative Law and Regulatory Practice 2002-2003

Jeffrey S. Lubbers, Editor

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Supervising Research with Human Subjects

By Lars Noah¹

In a provocative new article dealing with institutional review boards (IRBs), Professor Carl Coleman explains that these entities sometimes do an inadequate job of reviewing protocols before they approve proposed research involving human subjects. See Carl H. Coleman, *Rationalizing Risk Assessment in Human Subject Research*, 46 ARIZ. L. REV. 1 (2004). This is an important point that other commentators have failed to emphasize.

In identifying the root causes of this problem, however, Coleman has misunderstood the intended role of IRBs, and his proposed solutions may do more harm than good. He contends that IRBs should act less like juries and more like appellate courts without ever once recognizing that these boards much more closely (and appropriately) resemble peer review mechanisms utilized by the scientific community. Recasting these boards as adjudicatory bodies may appeal to those with training in the law, but the scientists and physicians who staff IRBs will recoil at any such suggestion. These boards cannot function properly if asked to operate in the fashion of the judiciary.

IRBs do not resemble judges and juries except in the most superficial of ways. For the most part, these boards consist of individuals with expertise generally relevant to the questions under review, their members may become actively involved in the process of acquiring information relevant to their decisions, and they enjoy some measure of continuity over time. It is entirely unrealistic and unwise to demand more structured analogical reasoning from IRBs using Coleman's suggestions for

mandatory opinion writing, some form of appellate scrutiny, an obligation to abide by precedent, and the issuance of general guidelines after public hearings. Efforts to promote consistency and transparency do not necessitate mimicking the judiciary.

Coleman repeatedly refers to the lack of any appellate scrutiny as granting IRBs unreviewable discretion, but this intentional feature of the arrangement actually promotes the goal of human subject protection. Although academic and other institutions that house IRBs may choose to review board decisions (perhaps at the behest of a patient advocate even though no formal mechanism exists for challenging board decisions to approve a protocol), the regulations expressly prevent these institutions from overriding an IRB decision to reject a protocol. See 21 C.F.R. § 56.112 (2003); 45 C.F.R. § 46.112 (2003). This asymmetry in granting unreviewable discretion may embolden boards by partially insulating them from the prospect of institutional pressures to placate disgruntled researchers or private sponsors.

Whether or not IRBs currently operate too much like juries, Coleman's suggestion for improved risk-benefit assessment in biomedical research seems seriously misguided for a number of reasons: it exaggerates the centrality of IRBs in existing systems of human subject protection, it incorrectly adopts a court-centered view of the processes used by other regulatory institutions, and it fails to appreciate some of the countervailing advantages of an under-proceduralized decisionmaking model. Human subject protection efforts suffer from many shortcomings, but it would be a terrible mistake to pursue solutions that recast boards as miniature appellate courts.

IRBs represent only one of several layers of protection against unethical and

potentially dangerous research on human subjects. Many studies that reach an IRB grow out of federal grants, which have already undergone scrutiny by the National Institutes of Health (NIH) or other funding agency, and most of the research that receives support from private industry requires initial clearance by the Food and Drug Administration (FDA).

Thus, one would hope that palpably foolish research would get nixed right from the start, even if unacceptably dangerous studies sometimes get past these initial efforts at screening. One also would hope that researchers at academic institutions have the sense to design clinical trials in ways that minimize the risk of injury to subjects and maximize the likely benefits to society, though here again the historical record – including some widely publicized recent mishaps – does not inspire confidence in relying entirely on an honor system. The FDA and the Department of Health and Human Services (HHS) occasionally do check up on IRBs, though not in the sense of reviewing particular decisions to approve protocols (at least not unless a scandal comes to light). Instead, the agencies spot-check IRBs for adherence to general procedural requirements.

Checks exist at the back-end of the process as well, which may help to discourage lapses in the first place. The FDA retains the power to place a “clinical hold” on previously approved research if problems emerge. In addition, the agency will not review clinical trials in support of a licensing application if they failed to comply with human subject protection rules. For other types of studies, researchers presumably will hope to publish their results. The editors of prestigious biomedical journals have taken a more active role in trying to regulate the nature of research underlying the articles that they publish, which means that

¹ Research Foundation Professor of Law, University of Florida. This is a condensed version of a more comprehensive piece titled, *Deputizing Institutional Review Boards to Police (Audit?) Biomedical Research*, 25 J. LEGAL MED. — (2004).

scientists eager for fame and fortune (or tenure) might take their responsibilities more seriously. Finally, the threat of tort liability imposed on researchers or their institutions may encourage increased vigilance in the future. In short, IRBs operate within a larger context that both checks their decisions and provides alternative safeguards for human subjects.

Coleman explicitly “starts with the premise that IRBs are engaged in a process of *legal* decision-making, insofar as they are interpreting specific regulatory requirements pursuant to authority that has been delegated to them by administrative agencies.” Although he quotes part of a sentence from my recently published casebook as support for this proposition, see LARS NOAH & BARBARA A. NOAH, *LAW, MEDICINE, AND MEDICAL TECHNOLOGY* 155 (2002) (“Is it appropriate for the FDA to delegate quasi-regulatory functions to such entities?”), I must take issue with his premise.

Although they can attempt to suspend or terminate research in the event of failures to abide by any conditions imposed at the time of protocol approval, IRBs do not exercise any real power to sanction wayward investigators or provide definitive interpretations of federal law. Instead, the FDA and HHS have decided to add an extra layer of protection to the research enterprise, requiring that investigators jump through still another hoop before pursuing their work. If a researcher chooses to proceed without receiving the blessing of a local board, he or she answers to federal officials for this and any other transgressions, and the investigator may face sanctions imposed by the institution for violating conditions of employment.

Although federal requirements for the creation and operation of IRBs may countenance the exercise of some delegated authority, the limited nature of this delegation counsels against recasting and proceduralizing boards as if they exercised the full panoply of powers vested in the FDA or HHS. Instead, the formal policy of relying on IRBs as front-line monitors adopted by these federal agencies in the 1970s represented an early version of what now goes under the banner of “audited self-regulation.” This

technique comes in many guises nowadays: companies of all types receive promises of prosecutorial leniency if they had corporate compliance programs in place, the SEC requires that publicly traded companies subject their financial statements to audits by independent accounting firms, hospitals participating in Medicare must establish peer review panels in order to monitor the quality of care delivered by physicians, and educational institutions receiving federal funds must undergo accreditation. These self-regulatory mechanisms do not involve the exercise of delegated governmental authority, and, notwithstanding their undoubted shortcomings as a substitute for the direct exercise of such authority, it would not make sense to propose reforms premised on an assumption that they acted in any such capacity.

Even if, for the sake of argument, we assume that IRBs act as deputized agents of federal regulators and play a central role in securing compliance with the law of human subject protection, it does not follow that these boards will function best only if they model themselves on their parent agencies. As one commentator explained: “Complying with the bureaucratic requirements typically imposed on agencies – following detailed procedures, providing hearings, defending decisions to review boards and courts – could frustrate the benefits of private participation in governance by imposing significant burdens.” Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543, 587 (2000). IRBs do not – and should not even attempt to – emulate the judiciary in pursuit of more consistent and transparent decisions. Instead of converting these boards into adversarial dispute resolution bodies, we should work to bolster their essentially inquisitorial approach to decisionmaking.

One of Coleman’s central concerns grows out of the inconsistency evident in the decisions made by different IRBs, and he thinks that a court-like approach will help to produce a body of common law that might bring order to this chaos. First, this would do little in a landscape of dispersed, as opposed to hierarchical, decisionmaking. Just as the courts in fifty

different states have failed to hit upon (and choose to follow) the single “best” answer to questions that arise in all sorts of private disputes, demanding that IRBs more clearly communicate their rationales with one another will not measurably increase the odds of developing anything approaching a consensus. The really tough issues, after all, have multiple plausible answers (as reflected in the published literature debating contested questions about research ethics) or arise in highly idiosyncratic cases. Even on the more seemingly straightforward methodological questions concerning study design, profound and largely irreconcilable disagreements often exist.

Coleman argues that IRBs should act more like administrative law judges (ALJs), federal employees who must produce written opinions – including explanations when they deviate from agency precedent – and face a form of appellate review within the agency. He fails, however, to recognize that these systems have not worked particularly well. See, e.g., Daniel J. Gifford, *Adjudication in Independent Tribunals: The Role of an Alternative Agency Structure*, 66 NOTRE DAME L. REV. 965, 968, 992–99 (1991). The experience with the federal disability benefits program run by the Social Security Administration (SSA), which uses more than 1,000 ALJs, offers a cautionary tale. With as many as 5,000 IRBs of various sorts in operation around the country, a comparable effort to achieve consistency in the field of human subject protection could not possibly succeed.

The experience with utilization review in the Medicare and Medicaid programs may offer an even more pertinent lesson. In 1972, Congress delegated “medical necessity” determinations to more than 200 regional professional standards review organizations (PSROs). In the course of holding that PSROs did not have to abide by the Freedom of Information Act, one court defended the decision to delegate utilization review functions to these panels: “It is preferable and appropriate that organizations of

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OMB's Revised Peer Review Bulletin

By Sidney A. Shapiro¹

In April 2004, the Office of Management and Budget proposed a "Revised Information Quality Bulletin on Peer Review." 69 Fed. Reg. 23,230 (April 28, 2004). The Bulletin will establish requirements for when agencies are required to obtain peer review of the information that they disseminate and provide a set of procedures for obtaining that peer review. The revised Bulletin replaces an earlier version proposed in September 2003, 68 Fed. Reg. 54,023 (2003) which drew 187 comments during the public comment period and which was the subject of an all-day public workshop at the National Academy of Sciences. OMB made substantial changes in the revised version, which it said were prompted by "many of the diverse perspectives and suggestions voiced during the comment period."

OMB cites as its principal legal authority to issue the Bulletin the Information Quality Act, which directed it to "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information" disseminated by the federal government.² It also claims authority to require peer review under Exec. Order 12866³ and under the "President's Constitutional authority to oversee the unitary Executive Branch." 69 Fed. Reg. at 23,233. OMB's legal authority, however, has been disputed by some commentators. One, the Center for Progressive Regulation, observed,

"Congress explicitly rejected the imposition of peer review a few years ago after due consideration and debate, and it is difficult to believe that Congress changed its mind when it passed the IQA. After all, the IQA was a rider hidden in an appropriations bill that no one in Congress other than the sponsor knew was there."⁴

Information Intended for Dissemination

Unless information has already been subject to adequate peer review, the revised proposal would require two levels of peer review, depending on the nature of the information being disseminated. Agencies are required to "have a peer review conducted on all 'influential scientific information' that the agency intends to disseminate," which "means scientific information the dissemination of which the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions." 69 Fed. Reg. at 23,240. The term scientific information means "factual inputs, data, models, analyses, or scientific assessments related to the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences." *Id.* For this type of information, OMB has permitted agencies to select a peer review mechanism appropriate for "the novelty and complexity of the science to be reviewed and the benefit and cost implications." Thus, "appropriate peer review mechanisms can range from review by qualified specialists within the Federal Government to formal review by an independent body of experts outside the Government," although peer reviewers must be "selected on the basis of necessary technical or scientific expertise, and should not have participated in development of the work product." *Id.*

OMB both narrowed the definition of when peer review is required and gave agencies greater flexibility concerning the type of peer review in response to critical comments that its prior requirement was too broad. For example, concerning the previous version of the Bulletin, the ABA wrote, "OMB is not triggering a peer review requirement on the basis of the complexity, novelty, or controversial nature of the scientific or technical information, when peer review may well play a positive role, but on how the information will be used. Peer review is simply not the correct mechanism to address the significant use of routine, established, or accepted scientific information."⁵

Despite these adaptations, some commentators maintained that the scope of the peer review requirement in the revised Bulletin was still too broad. The Center for Progressive Regulation, for example, commented, "OMB increases the breadth of its peer review requirement by including 'factual inputs' and 'data' in the category of influential information. . . . Requiring review of every factual input and piece of data that could have a substantial impact on public policy casts the peer review net too broadly and will create endless delays."⁶

Peer reviewers are subject to conflict of interest rules, which OMB rewrote to accommodate criticisms that it had previously unduly restricted the participation of government scientists and had failed to establish appropriate limitations on researchers who had industry contacts.⁷ For reviewers who are not serving as federal employees (to whom federal conflict of interest regulations apply), agencies must either "apply or adapt the federal ethics requirements for reviewers who are not federal employees." 69 Fed. Reg. at 23,240. In adapting the federal regulations, OMB requires agencies to "consider the conflict of interest policy used by the National Academy of Sciences, including principles regarding potential financial conflicts arising from

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²Public Law 106-554, §515(a).

³58 Fed. Reg. 51735 (1993).

⁴Letter to Dr. Margo Schwab from the Center for Progressive Regulation (Dec. 7, 2003), at 3.

⁵Letter to Dr. Margo Schwab from American Bar Association (Dec. 23, 2003), at 2.

⁶Letter to Dr. Margo Schwab from the Center for Progressive Regulation (May 27, 2004), at 3.

⁷See, e.g., Letter to Dr. Margo Schwab from Public Citizen (Dec. 15, 2003), at 5.

factors such as a reviewer's investments, employer and business affiliations, grants, contracts and consulting income." *Id.*

Although OMB gives agencies flexibility to design the peer review process for this type of information, it does require agencies to make available to the public a "detailed summary or copy of the reviewers' comments, as a group or individually" and to include this summary where appropriate as "part of the administrative record for related agency actions." *Id.* OMB also requires agencies to consider the comments of the reviewers. *Id.*

Scientific Assessments

For a second type of information, OMB has proposed a more prescriptive set of rules concerning peer review but would permit an agency to undertake the peer review itself or "commission entities independent of the agency to select peer reviewers and/or manage the peer review process in accordance with [the Bulletin]." *Id.* at 23,241. These rules would apply to any "influential" scientific information that an agency or OMB's administrator determines is a "scientific assessment" if the information meets one of two tests. The rules would apply if the information could have "a clear and substantial impact on important public policies (including regulatory actions) or private sector decisions with a potential effect of more than \$500 million in any year," or if the information involves "precedent setting, novel, and complex approaches, or significant interagency interest." *Id.* at 23,240. Information constitutes a "scientific assessment" when it contains "an evaluation of a body of scientific or technical knowledge which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information." *Id.* These assessments include "state-of-science reports, technology assessments, weight-of-evidence analyses, meta-analyses, risk assessments, toxicological profiles of substances, integrated assessment models, hazard determinations, exposure assess-

ments, or health, ecological, or safety assessments." *Id.*

For this type of information, OMB adds an "independence" requirement to its conflict of interest rules. Agencies are required to "bar participation by scientists employed by the agency sponsoring the review unless the reviewer's service as a peer reviewer defines the government employment (i.e., special government employees)," to "consider requesting the nomination of potential reviewers based on expertise and objectivity from the public, including scientific and professional societies," and to "consider the prevailing selection practices of the National Academy of Sciences concerning ties of a potential committee member to the sponsoring agency." *Id.* at 23, 240-41. OMB clarified that research grants that are awarded to scientists based on investigator-initiated, competitive, peer reviewed proposals "generally do not raise issues as to independence or conflicts," *id.* at 23, 241, after it received comments that its prior proposal appeared to have disqualified such scientists.⁸

OMB imposes three additional requirements for this category of peer review. First, the agency or entity managing the peer review for the agency must "provide the reviewers with sufficient information – including background information about key studies or models – to enable them to understand the data, analytic procedures, and assumptions used to support the key findings or conclusions of the draft assessment." 69 Fed. Reg. at 23,241. Reviewers are also to "be informed of applicable access, objectivity, reproducibility and other quality standards under the federal laws governing information access and quality."

Second, if an agency has prepared a draft scientific assessment and made it available to the public prior to or during peer review, OMB requires the agency "whenever practical" to provide "a compilation or summary of relevant public comments on the draft assessment that address significant scientific or technical issues" to peer reviewers. *Id.* Further, when "there is sufficient public interest, the agency – or entity managing the peer Review – shall consider establishing a

public comment period for a draft report and sponsoring a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested members of the public." *Id.*

Third, peer reviewers must prepare a report that describes the nature of their review, their findings and conclusions, and that either "summarize[s] the views of individual reviewers (either with or without specific attributions, as long as the reviewers are informed in advance of the agency's plans for disclosure) or represent[s] the views of the group as a whole (including any dissenting views)." *Id.* OMB further requires that the report "disclose the names, organizational affiliations, and a short paragraph on the credentials and relevant experiences of each peer reviewer." *Id.* After an agency receives the report, it is required to prepare a written response indicating its "agreement or disagreement; any actions the agency has undertaken or will undertake in response to the report; and (if applicable) the reasons the agency believes those actions satisfy any key concerns or recommendations in the report." *Id.* Finally, OMB requires agencies to "disseminate the final peer review report and the agency's written statement of response on the agency's Web site, and all the materials related to the peer review (charge statement, peer review report, and agency response) shall be included in the administrative record for any related agency action." *Id.*

Conclusion

OMB requires agencies to post a list of planned and ongoing peer reviews indicating the type of information being reviewed according to the two categories that OMB has established. *Id.* This listing must provide information that OMB has specified including whether peer reviewers will be selected by the agency or by an outside organization, whether members of the public will be asked to nominate potential peer reviewers, and whether members of the public will be able to comment on the work product to be peer reviewed.

OMB's deadline for public comment was May 28, 2004. It is unknown when it might issue a final version of the Bulletin.

⁸See, e.g., Public Citizen Comments, *supra* note 8.

While generally supported by the business community, OMB's first attempt at designing a peer review Bulletin was deeply controversial among public interest groups⁹ and among many scientists.¹⁰ The revised Bulletin is likely to satisfy many of the scientists who opposed the earlier version, but the new version is

unlikely to gain the support of environmental and similar public interest groups. Few people doubt the value of peer review as an important aid to the development of sound government policy. The question is when and how should such peer review be employed. ○

⁹ See, e.g. David Kohn, "Foes say Bush plan would create debating society over science: Health, environmental rules could be buried in peer reviews, critics fear," *Baltimore Sun* (Dec. 18, 2003).

¹⁰ See, e.g., Robert Steinbrook, "Peer Review and Federal Regulations," 350 *NEW ENG. J. MED.* 103 (2004).

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professionals undertake review of members of their profession rather than for Government to assume that role.... The purpose here is to assure that only doctors knowledgeable in the provision and practice of hospital care will review such care." *Public Citizen Health Research Group v. HEW*, 668 F.2d 537, 542-43 (D.C. Cir. 1981). The court added that, by rendering "conclusive" (i.e., unreviewable) decisions about coverage, "they do not and should not become part of a government organization.... [A]ny other arrangement would be impractical: if the Department undertook to review each of the hundreds of thousands of medical opinions submitted the result would be the creation of an unworkable bureaucratic monster." *Id.* at 544.

PSROs often sub-delegated their tasks to existing hospital utilization review committees. Although hospitals have relied on a peer review process in making credentialing and quality assurance decisions for at least the last half century, this approach suffers from many of the same limitations that critics say affect IRB operations, including conflicts of interest and a lack of rigor, consistency, and transparency. As with IRBs, however, hospital peer review represents just one of many imperfect quality control mechanisms used in medicine, and encumbering the process with additional procedures probably would make things

worse rather than better. PSROs faced some centralized review, but continuing inconsistencies led Congress to replace these essentially local panels with state-level peer review organizations just one decade later. At least initially, however, the shift did little to resolve these concerns.

Informal exchanges of ideas would, of course, promote efficiency in the sense that each IRB would not have to reinvent the wheel when it first encounters a difficulty that has arisen elsewhere previously, but IRBs already have informal networks designed to accomplish this purpose. An active listserv exists in this community alongside reference volumes and specialized periodicals, to say nothing of the various professional journals that routinely publish items about research ethics. The mandatory publication of formal opinions by IRBs would add little to this dialogue.

Coleman also argues that mandatory opinion writing and review would promote transparency. The obligation to spell out on paper and then defend a decision to proceed with a particular experiment involving human subjects undoubtedly would promote reflection, but, in placing this obligation on the IRB, he has focused on the wrong actor. It may make more sense to view the principal investigator as the source of the preliminary risk-benefit assessment and the IRB as the designated (and final)

appellate body. If IRBs had to provide explanations and then anticipate appeals from the only party likely to press them (namely, a dissatisfied investigator), then they may become paralyzed with the overwhelming workload, or else they might become more "gun shy" about ever rejecting protocols unless a patient advocate had the opportunity to challenge such approval decisions. On that score, the unintended consequences of the revolution in procedural due process as well as judicial review of informal agency rulemaking should inspire caution. Judges naturally thought that imposing a duty to listen and then offer an explanation would help to prevent inaccurate and unfair decisions, but the flaws in this assumption have become apparent with time.

In the area of human research subject protection, better guidance from the FDA, HHS, and NIH would have the dual benefit of minimizing inconsistency and relieving already overburdened IRBs. In contrast, Coleman's central proposals would not do much to reduce the former problem, and they might seriously worsen the latter difficulty. Undoubtedly this represents an overly idealized view of how IRBs operate in practice, but it does offer an ideal toward which they should strive. An appellate ideal, in contrast, would take boards in entirely the wrong direction. ○

***The Section values the input of all its members. Make your opinion count.
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you get more involved with Section activities.***

Mead and Tax Law

By Ellen Aprill,¹ Linda Galler² and Irving Salem³

United States v. Mead Corporation, 533 U.S. 218 (2001), emphasized “the great variety of ways in which the laws invest the Government’s administrative arms with discretion, and with procedures for exercising it, in giving meaning to Acts

of Congress,” *id.* at 235–36. *Mead* thus underscores the need for an agency-by-agency consideration of the extent to which courts should give deference to administrative pronouncements under the mandate of *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

As tax lawyers, we believe that there are ways in which tax law is unusual, if not unique, when compared to other areas of administrative law. This article will briefly discuss three areas in which tax law seems to follow its own peculiar set of principles: (1) the difference between interpretive and legislative regulations; (2) Supreme Court jurisprudence regarding deference to regulations; and (3) the attitude of the Tax Court toward revenue rulings. These features make an agency-specific approach particularly appropriate for tax law but also make applying the tests of *Mead* difficult.

I. Interpretive and Legislative Tax Regulations

As the readers of this publication are well aware, the Administrative Procedure Act (“APA”) defines a “rule” as “the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency.” 5 U.S.C. § 551(4). The APA requires agencies to follow notice and comment procedures when they promulgate these legislative rules that bind the public. 5 U.S.C. § 553(b). The APA explicitly exempts from the notice and comment requirements “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice.” *Id.*

Tax law traditionally has used a different basis to distinguish between legislative and interpretive regulations. Section 7805(a) of the Internal Revenue Code (the “Code”) grants a general rule-

making authority to the Secretary of Treasury. In other areas of the law, grants of authority similar to that of § 7805 are deemed to be grants to promulgate legislative rules carrying the force of law.⁴ Such has not been the case for tax law. Tax law reserves the category “legislative” regulations for regulations promulgated pursuant to grants of regulatory authority under specific substantive provisions of the Internal Revenue Code.⁵

In tax parlance, regulations promulgated under the general authority of § 7805(a) are considered interpretive regulations. Moreover, in promulgating interpretive regulations, the IRS invariably specifies that “section 553(b) of the Administrative Procedure Act (5 U.S.C. § 553) does not apply to these regulations.”⁶ At the same time, however, it is the customary practice of the IRS to follow notice and comment procedures for interpretive regulations.⁷

In cases pre-dating *Chevron*, the Supreme Court accepted this distinction between tax legislative and tax interpretive regulations in determining the proper level of deference. The Supreme Court wrote in *Rowan Cos. v. United States*, 452 U.S. 247, 253 (1981), and reiterated in *United States v. Vogel Fertilizer*, 455 U.S. 16, 24 (1982), that when a regulation is issued under the general authority of § 7805(a), “we owe the interpretation less deference than a regulation issued under a specific grant of authority to define a statutory term or prescribe a method of executing a statutory provision.”

Mead decreed that “administrative implementation of a particular statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law and that the agency interpretation claiming deference was promulgated in the exercise of that authority.” 533 U.S. at 226–27.

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⁴See Thomas W. Merrill & Kathryn Tongue Watts, *Agency Rules with the Force of Law: The Original Convention*, 116 HARV. L. REV. 467 (2002); *United States v. Haggard Apparel Co.*, 526 U.S. 380 (1999); *United States v. O’Hagan*, 521 U.S. 642 (1997); *Sullivan v. Zebley*, 493 U.S. 521 (1990).

⁵See Merrill & Watts, *supra* note 1; Ellen P. Aprill, *Muffled Chevron: Judicial Review of Tax Regulations*, 3 FLA. TAX REV. 51, 55–57 (1996). Perhaps the most famous of such regulatory grants is section 1502 of the Code: “The Secretary shall prescribe such regulations as he may deem necessary in order that the tax liability of any affiliated group of corporations making a consolidated return and of each corporation in the group, both during and after the period of affiliation, may be returned, determined, computed, assessed, collected, and adjusted in such manner as clearly to reflect the income tax liability and the various factors necessary for the determination of such liability, and in order to prevent avoidance of tax liability.” With this grant of regulatory authority, Congress left it to Treasury and the IRS to work out the details of the consolidated return regime.

⁶See, e.g., T.D. 9043, 68 Fed. Reg. 10,190 (2003). Section 30(15) of the Internal Revenue Manual, which comprises the Regulations Drafting Handbook, is consistent on this point: “5 U.S.C. 553(b) requires that a notice of proposed rulemaking be published in the Federal Register and that interested persons be given the opportunity to comment on the proposed regulations before final regulations are adopted However, these requirements do not apply if the rules are interpretative.”

⁷For recent examples, see Supplemental Proposed Regulations on Equity Split Dollar Life Insurance, 68 Fed. Reg. 24,898 (2003); Proposed Regulations on Changes in Accounting Method, 68 Fed. Reg. 25,310 (2003); Proposed Regulations on Private Activity Bond Definition, 68 Fed. Reg. 25,845 (2003).

The opinion continues, “Delegation of such authority may be shown in a variety of ways, as by an agency’s power to engage in adjudication or notice-and-comment rulemaking, or by some other indication of a comparable congressional intent.” *Id.*

This language from *Mead* has made the degree of deference due interpretive tax regulations uncertain. The IRS states that is not acting under § 553(b) of Administrative Procedure Act when it promulgates interpretive regulations. It does, nonetheless, rely on § 7805(a) and use notice and comment procedures. Furthermore, Treasury Regulation § 601.601(a)(1) states: “Internal Revenue rules take various forms. The most important rules are issued as regulations and Treasury decisions prescribed by the Commissioner and approved by the Secretary or his delegate.” This characterization does not distinguish between legislative and interpretive regulations.

Some commentators and courts have concluded that, under the tests of *Mead*, interpretive tax regulations are not entitled to *Chevron* deference. For example, Judge Vasquez, dissenting in *Robinson v. Commissioner*, 119 T.C. 44, 119–20 (2002), concluded that, under *Mead*, interpretive regulations issued relating to the deductibility of interest on federal income tax deductions were not entitled to *Chevron* deference because they were not issued pursuant to a “specific congressional delegation of authority having the force and effect of law.”⁸ Other courts have continued to give interpretive tax regulations *Chevron* deference. See *Marsh & McLennan v. United States*, 302 F.3d 1363 (Fed. Cir. 2002). Furthermore, as discussed in the next section, a recent Supreme Court case, *Boeing Company v. United States*, 537 U.S. 437 (2003), required deference to an interpretive tax regulation. Thus, this important issue remains unsettled.

⁸For discussions by commentators who agree with this analysis, see John F. Coverdale, *Chevron’s Reduced Domain: Judicial Review of Treasury Regulations and Revenue Rulings After Mead*, 55 ADMIN. L. REV. 39 (2003); Mitchell M. Gans, *Deference and the End of Tax Practice*, 36 REAL PROP., PROB. & TRUST J. 731 (2002).

II. Supreme Court and Deference to Tax Regulations

Rather than looking to *Mead* and *Chevron*, the Supreme Court in tax cases frequently has relied instead on a line of Supreme Court tax jurisprudence to decide whether a tax regulation is reasonable. The fullest statement of this reasonableness test came in *National Muffler Association v. United States*, 440 U.S. 472 (1978). Upholding a denial of tax exemption for a trade association pursuant to standards described in a regulation under § 501(c)(6) of the Code, which was promulgated under the general authority of § 7805(a), *National Muffler* tested the reasonableness of the regulation according to such factors as the extent to which it harmonized with the plain language, origin, and purpose of the statute; the manner in which the regulation evolved; the length of time the regulation had been in effect; the reliance placed upon it; the consistency of interpretation; and the degree of scrutiny Congress had devoted to it. 440 U.S. at 477. *National Muffler* concluded that although the regulation at issue in the case was “not the only possible” reading of the statutory language, it merited “serious deference” under the factors listed, *id.* at 484, and that “[t]he choice among reasonable interpretations is for the Commissioner, not the courts,” *id.* at 488.

Without comment, the Supreme Court has adhered to the reasonableness test of *National Muffler* in its tax cases dealing with regulations decided since *Chevron*. For example, in *Cottage Savings Ass’n v. Commissioner*, 449 U.S. 554 (1991), the issue was whether a financial institution realized tax-deductible losses when it exchanged its interest in one group of residential mortgage loans for another lender’s interests in a different group of residential mortgage loans. To answer that question, the Court looked to Treasury Regulation § 1.1001-1, promulgated under the general authority of § 7805(a), which construed the statutory phrase “disposition of property” in § 1001 of the Code as requiring a material difference in the properties exchanged. The opinion cites *National Muffler* in explaining that a court must

defer to the Commissioner’s regulatory interpretations of the Code so long as they are reasonable. 499 U.S. at 561.

Cottage Savings concluded that the regulation was reasonable because both the statutory language and the IRS requirement of a material difference were longstanding and because the material difference requirement was consistent with the Court’s own landmark precedent on realization. The case did not so much as cite *Chevron*, which had been decided seven years earlier.

Most recently, in *Boeing Company v. United States*, 537 U.S. 437 (2003), the Court ignored both *Chevron* and *Mead*, despite the lower court’s reliance on *Chevron* in its opinion and the government’s reliance on both *Chevron* and *Mead* in its briefs. In *Boeing*, the Court upheld Treasury Regulation § 1.861-8(e)(3), which allocates research and development expenses between domestic and foreign sources, as applied to a domestic international sales corporation (“DISC”) by virtue of a cross-reference in Treasury Regulation § 1.994-1(c)(6)(iii). The Treasury Department, the opinion explains, could have promulgated a regulation addressing the proper allocation of research and development costs between the parent and its DISC subsidiary under specific authority delegated to it in § 994 of the Code, but instead promulgated the regulation under the general authority of § 7805(a). The Court decided that even if the regulation at issue were regarded as “interpretive because it was promulgated under section 7805(a)’s general rulemaking grant rather than pursuant to a specific grant of authority,” a court “must still treat the regulation with deference.” 537 U.S. at 448. The opinion relies solely on *Cottage Savings* for this proposition. It does not mention *Mead*, *Chevron*, or as *Mead* might suggest *Skidmore v. Swift & Co.*, 323 U.S. 1334 (1944).

Readers of the Court’s post-*Chevron* tax opinions are left wondering whether the Court applies a unique analysis when deciding cases involving deference to IRS interpretations of the tax law. The cases have left and continue to leave the relationship between *Chevron* and *National Muffler* unresolved.

III. Revenue Rulings and the Tax Court

The appellate court decision in *Mead* compared the tariff rulings at issue there to revenue rulings. See *Mead v. United States*, 185 F.3d 1304, 1307 (Fed. Cir. 1999). Revenue rulings are official interpretations published in the Internal Revenue Bulletin as the IRS's legal conclusions based on stated facts. Treasury Regulation § 601.601(d)(2)(i)(a); Rev. Proc. 2003-1, 2003-1 I.R.B. 1. They are an important source for administrative interpretations of the tax law. In 2003, for example, the IRS issued 128 revenue rulings.⁹ Revenue rulings are issued only by the IRS national office. The IRS describes revenue rulings as promoting uniform application of the tax laws and assisting taxpayers in attaining maximum voluntary compliance.¹⁰ The weekly Internal Revenue Bulletin states explicitly that revenue rulings and revenue procedures "do not have the force and effect of Treasury Department Regulations, but they may be used as precedents." Moreover, revenue rulings make no reference to § 7805(a).

The Court of Appeals for the Federal Circuit, in *Mead*, comparing trade and tax matters, observed that "Customs' classifications rulings are in some ways an even less formalized body of interpretations than IRS revenue rulings." 185 F.3d at 1307. If, according to the Supreme Court in *Mead*, customs tariff classifications deserve deference under *Skidmore*, it is unclear whether the more formalized body of interpretations represented by revenue rulings requires the higher deference of *Chevron* or whether they merit application only of *Skidmore*, perhaps with consideration of additional, or different, factors. The Supreme Court in *Mead* chose not to explore the revenue ruling analogy.

Mead has complicated the calibration of judicial deference due revenue rulings. The Tax Court has traditionally afforded revenue rulings no deference whatsoever,

while the federal appellate courts prior to *Mead* varied.¹¹ Cases since *Mead* have taken differing approaches to the weight due revenue rulings. For example, in *Omohundro v. United States*, 300 F.3d 1065 (9th Cir. 2001), the Court of Appeals for the Ninth Circuit unambiguously concluded that the "Supreme Court decision in *Mead* ... requires that we accord *Skidmore* deference to revenue rulings." 300 F.3d at 1069. In *Vons Companies, Inc. v. United States*, 51 Fed. Cl. 1 (2001), the Court of Federal Claims reiterated its view, in a discovery order, that revenue rulings are not binding precedent but do require consideration. 51 Fed. Cl. at 8. In a footnote, the order suggests that *Mead* and other recent Supreme Court cases call into question any decisions that give revenue rulings the force of precedent under *Chevron*. *Id.* at 8 n.5.

If *Mead* does apply to tax law, *Mead's* invocation of *Skidmore* for tariff rulings would seem to undermine the Tax Court's traditional refusal to grant any deference to revenue rulings. And it appears the Tax Court is beginning to notice. In *Lunsford v. Commissioner*, 117 T.C. 159 (2001), Judge Halpern's concurring opinion acknowledges the Tax Court's historical view that revenue rulings receive no deference because they are merely opinions of a lawyer in the agency, while referring to *Mead* in a "but see" citation, "for a discussion of the deference, but less than *Chevron* deference, owed to certain agency interpretations of a statute." 117 T.C. at 174 n.6 (Halpern, J., concurring). Similarly, the court in *Medical Emergency Care Associates v. Commissioner*, 120 T.C. 436 (2003), declined to defer to a revenue

ruling, but only after discussing *Mead* and *Mead's* invocation of *Skidmore*, and only after concluding that "we are unable to ascertain the thoroughness of the agency's consideration or the validity of its reasoning."

Insofar as *Mead* calls for deference to revenue rulings by the specialized Tax Court, it has important implications for our understanding of *Skidmore*. *Skidmore*, unlike *Chevron*, does not rely on theories of Congressional delegation, but on factors, such as expertise, that reflect the capacity and competence of administrative agencies. Specialized courts, of course, are themselves expert. The case of revenue rulings highlights the tensions inherent in application of *Skidmore* by specialized courts.

IV. Conclusion

We believe that it is useful and important for administrative law scholars to be informed about the peculiarities of tax law. Given the pervasiveness of the IRS in our lives, consideration of judicial deference to administrative interpretations that fails to take tax law into account will be incomplete.

Our purpose here has been to describe some aspects of tax law that make application of *Mead* particularly difficult in this area. Comprehensive consideration of these and other issues as well as our recommendations regarding judicial deference to administrative interpretations of tax law can be found in the ABA Section of Taxation Report of the Task Force on Judicial Deference in the Spring 2004 issue of *The Tax Lawyer*. The report is also available at <http://www.abanet.org/tax/pubs/ttl/572sp04/juddef.pdf>. 

⁹ 2003-50 I.R.B. 1211.

¹⁰ Rev. Proc. 1989-14, 1989-1 C.B. 814, 814-15.

¹¹ See Linda Galler, *Judicial Deference to Revenue Rulings: Reconciling Divergent Standards*, 56 OHIO ST. L.J. 1037 (1995).

In Memoriam

The Section mourns the passing of Dr. Michael Belkin, the husband of former Section Chair and longtime Section leader Janet Belkin. Mike passed away on May 28, after a bout with a rare form of cancer.

Mike attended many Section functions with Janet, and his gentle presence always added to the good humor and good spirit of those meetings.

The Section extends its sincerest condolences to Janet and her family.



Section of Administrative Law and Regulatory Practice

2004 Annual Meeting

Co-Located at the Westin Peachtree Plaza and the Georgia World Congress Center

August 6 – 8, 2004

Sponsored by Alston & Bird, Sutherland Asbill & Brennan and Wiley, Rein & Fielding

Conference Chair: Myles Eastwood, Atlanta, Georgia

For registration information phone (202) 662-1528, or email KnightK@staff.abanet.org

FRIDAY, AUGUST 6, 2004

9:30 am – 11:00 am

Federal Preemption of State Laws: Repercussions for the Banking Industry

Georgia World Congress Center/Presidential CLE Center
Room A409/Level 4

Federal preemption of state laws in the areas of predatory lending, privacy, securities law enforcement, and insurance and its relationship with state enforcement of laws continues to generate controversy and new rulemaking. This session will examine preemption and what it means for consumers and regulated entities and how the states are responding.

Panelists:

- **Charlotte Bahin**, Director of Regulatory Affairs, America's Community Bankers

Other Speakers TBA

2:00 pm – 4:30 pm

"Accountability & Access Issues in Homeland Security"

Georgia World Congress Center/Presidential CLE Center
Room A409/Level 4

Conflicts of secrecy, anti-terrorism efforts, and public openness have grown as the privacy considerations of Homeland Security have become evident. The panel will reflect varied perspectives and debate ways and means of keeping government accountable for these critical roles.

Co-sponsored by the Military Law Committee of the General Practice, Solo & Small Firm Section and the State & Local Government Law Section

Panelists:

- **Ernest Abbott**, FEMA Law Associates, PLLC
- **Gary Bass**, Founder and Executive Director, OMB Watch
- **Christopher Drew**, Writer, New York Times
- **Tom Madden**, Partner, Venable LLP
- **Jim O'Reilly**, Professor, University of Cincinnati School of Law
- **Tom Susman**, Partner, Ropes & Gray LLP
- **Joe Whitley**, General Counsel, U.S. Department of Homeland Security

Moderator: Lynne Zusman, Lynne K. Zusman and Associates, P.C.

3:45 pm – 5:15 pm

"Phishing" in International Waters: Law Enforcement and Regulatory Responses to Online Identity Theft

Georgia World Congress Center/Presidential CLE Center
Room A310/Level 3

This program will focus on one of the most significant concerns for financial institutions and e-commerce companies in online commerce: "phishing" (i.e., using emails and websites that look like legitimate companies' emails and websites to persuade people to disclose their identifying and financial account data, and using the results for identity theft and fraud). "Phishing" and other forms of online identity theft have become increasingly problematic for law enforcement and regulators as well, in part because many of these schemes operate internationally and the task of even shutting down spurious websites hosted in foreign jurisdictions has proved problematic for major companies. This

program will explain how phishing schemes work, why they pose significant risks to businesses and consumers, and what government agencies and private-sector organizations are doing to combat the problem.

Co-sponsored by the Section of International Law and Practice and the Criminal Justice Section

Panelists:

- **Sana Coleman**, Bureau of Consumer Protection, Federal Trade Commission
- **David Jevan**, Chairman, Anti-Phishing Working Group and Vice-President, Tumbleweed Communications
- **Jonathan Rusch**, Special Counsel for Fraud Prevention, U.S. Department of Justice

6:00 pm

Shuttle Transportation to Section Reception and Dinner

Peachtree Street Entrance, Westin Peachtree Plaza

6:30 pm – 9:30 pm

Section Reception and Dinner at Anthony's

3109 Piedmont Road (Buckhead area)

Housed in an antebellum mansion built in 1797, **Anthony's Restaurant** offers the finest cuisine, both continental and contemporary Southern. Tickets are \$85.00 for Members; \$95.00 Non-Members.

SATURDAY, AUGUST 7, 2004

8:00 am – 9:00 am

Membership Committee Meeting

Boardroom - Westin Peachtree Plaza

8:00 am – 9:00 am

Section Continental Breakfast

International D/E—Level 6 Westin Peachtree Plaza

9:00 am – Noon

Section Council Meeting

International D/E—Level 6 Westin Peachtree Plaza

9:30 am – 11:30 am

"Is It Safe?" Infrastructure Security—How, When and Who Pays?

Georgia World Congress Center/Presidential CLE Center Room A313/Level 3

This panel will address the challenges facing public utilities, communications providers and transportation carriers from threats to national security and the targeting of these industries by enemies of the United States of America. Speakers will discuss the respective roles and responsibilities of government and industry to prevent and mitigate attacks on infrastructure targets,

the legal aspects of counter measures, and how the costs of these efforts should be allocated.

Co-sponsored with The Section of Public Utility, Communications and Transportation Law

Noon – 1:00 pm

Publications Committee Meeting

Boardroom Westin Peachtree Plaza

2:00 pm – 3:30 pm

Ethics for Environmental Practitioners

Georgia World Congress Center/Presidential CLE Center Room A409/Level 4

This program will focus on ethical issues often encountered by environmental law practitioners. Attendees will be engaged in case studies and follow-up discussions.

Co-sponsored by The Standing Committee on Environmental Law

Panelists:

- **Blake A. Biles**, Partner, Arnold & Porter
- **Cynthia Drew**, Professor, University of Miami School of Law
- **Irma Russell**, Professor, University of Missouri at Kansas City (UMKC) School of Law

SUNDAY, AUGUST 8, 2004

7:30 am – 9:00 am

Section Women's Networking Breakfast

Westin Peachtree Plaza Café Restaurant/ RSVP Required

8:00 am – 9:00 am

Section Continental Breakfast

International D/E—Level 6 Westin Peachtree Plaza

9:00 am – Noon

Section Council Meeting

International D/E—Level 6 Westin Peachtree Plaza

9:30 am – 11:30 am

"The August 14 Blackout –Anomaly or Harbinger?" Grid Stability—Is Our Electricity System Reliable?

Georgia World Congress Center/Presidential CLE Center Room A313/Level 3

Panelists will address the lessons learned from the August 14 blackout and how regulators and electric utilities are responding to those lessons. Topics will include the cooperation and tension between federal and state regulatory authorities, liability for blackout losses and related insurability issues, whether deregulation has impaired system reliability, and how the costs of grid enhancements should be borne.

Co-sponsored with the Section of Public Utility, Communications and Transportation Law

Supreme Court News

By William Funk¹

As this issue of the News goes to press, the big cases outstanding involve the rights of those swept up in the war on terror. Nevertheless, there have been a number of little remarked and unremarkable administrative law/regulatory practice cases before the very end of term, and on May 17 a flurry of federalism cases. In these latter cases, the Court issued decisions in three cases dealing with constitutional limits on Congress's lawmaking authority.

In *Tennessee Student Assistance Corp. v. Hood*, 124 S.Ct. 1905 (2004), the Court granted certiorari to decide whether Congress's authority under the Bankruptcy Clause of Article I trumps states sovereign immunity recognized in the Eleventh Amendment, but in an opinion by Chief Justice Rehnquist the Court ducked that question by holding that the discharge of a student debt to a state in Bankruptcy Court is an exercise of *in rem jurisdiction* rather than an exercise of jurisdiction over a state. Consequently, it did not raise an Eleventh Amendment question. Justice Thomas, joined by Justice Scalia, dissented.

In *Sabri v. United States*, 124 S.Ct. 1941 (2004), Sabri was charged with violating the federal criminal prohibition on bribing an agent of an organization receiving more than \$10,000 a year from the federal government. He defended on the basis that the law exceeded Congress's power under the Spending Clause, because it did not require that his bribe actually related to some use of federal money. The Court's opinion by Justice Souter held that it was well within the Necessary and Proper Clause for Congress to criminalize any corrupt dealings with persons associated with organizations receiving federal funds without requiring proof that the integrity of the federal funds was affected. Money is fungible, the Court said, so that a waste of some of the organization's funds was likely to impact the federal funds, and corruption within the organization would be a threat to the appropriate use of federal funds. Elimination of those threats to the correct expenditure of federal funds satisfied the means-end rationality described in *McCulloch v. Maryland*, 4 Wheat. 316 (1819). This opinion was joined by all except Justice Thomas, who, while he would have upheld the statute under Commerce Clause precedents, expressed the view that *McCulloch* requires more than mere means-end rationality. He believes there must be "some obvious, simple, and direct relationship between the statute and the enumerated power."

The Court's opinion "add[ed] an afterword on Sabri's technique for challenging his indictment by facial attack." This technique, the Court said, is "especially to be discouraged." While this "afterword" did not mention either *United States v. Lopez*, 514

U.S. 549 (1995), or *United States v. Morrison*, 529 U.S. 598 (2000), the two modern cases finding statutes beyond Congress's Commerce Clause power, both of which might be characterized as facial attacks, it provoked Justice Kennedy, joined by Justice Scalia, not to join this part of the opinion and to reaffirm "the practice we have followed in cases such as [these.]"

Tennessee v. Lane, 124 S.Ct. 1978 (2004), involved a claim that Congress exceeded its authority under Section 5 of the Fourteenth Amendment in enacting Title II of the Americans with Disabilities Act, which prohibits excluding disabled persons from the benefits of the activities of a public entity. The case arose in the increasingly common situation of a suit against a state for damages and the state's invocation of a claim of sovereign immunity under the Eleventh Amendment, but it presented the perhaps unique facts of a wheelchair bound criminal defendant dragging himself up the stairs to a second floor courtroom in order to appear for trial.

In 2001 the Court by a 5-4 vote had held that Title I of the ADA, prohibiting discrimination against disabled persons in employment, was not a valid exercise of Congress's Section 5 power, *Bd. of Trustees of Univ. of Ala. v. Garrett*, 531 U.S. 356, but it expressly did not reach Title II. In *Tennessee v. Lane*, however, Justice O'Connor switched sides, resulting in a 5-4 decision upholding the claim against the state as within Congress's power under Section 5. Two factors, the Court said, distinguished this case from the earlier case. First, whereas in *Garrett* there was little or no evidence of past unconstitutional discrimination in employment of disabled persons by states, here there was substantial evidence of state discrimination against the handicapped in the provision of public benefits. Second, whereas in *Garrett* the applicable constitutional test for determining constitutionality of state action was the undemanding rational relationship test, here, because the claim involved the deprivation of a fundamental right – access to a court – the test was much stricter. Consequently, the Court held that Congress's response was congruent and proportional to the constitutional violations it found.

Justice Rehnquist, joined by Justices Kennedy and Thomas, disagreed on two counts. First, in his view the evidence here of unconstitutional state action was not stronger than in *Garrett*. Second, he believed Title II should be viewed generally – as extending to all public accommodations – not just to courts, the public accommodation involved here.

Justice Scalia dissented for a different reason. He confessed error for having concurred in the original test of congruency and proportionality for determining the proper exercise of Congress's Section 5 powers. It is, he said, too indeterminate and "is a standing invitation to judicial arbitrariness and policy-driven decision making." He would limit Congress's Section 5 power to "enforcing" constitutional requirements; he would not

¹ Professor of Law, Lewis & Clark Law School; Section Chair; and Contributing Editor.

allow any prophylactic measures – “prohibiting primary conduct that is itself not forbidden by the Fourteenth Amendment.”

As for the administrative law cases: a plain jane administrative law case is *Household Credit Services, Inc. v. Pfennig*, 124 S.Ct. 1741 (2004), in which the issue was whether a bank’s fee for exceeding a credit limit on a credit card (an over-limit fee) is a “finance charge” within the meaning of the Truth in Lending Act. If such a fee is a “finance charge,” then it must be identified as a finance charge on customers’ bills, and the over-limit fees were not so identified. The Act defines “finance charge” as an amount “payable directly or indirectly by the person to whom the credit is extended, and imposed directly or indirectly by the creditor as an incident to the extension of credit.” The Federal Reserve Board, however, to whom the Act delegates the responsibility for enacting regulations to implement the Act, adopted Regulation Z, specifically excluding over-limit fees from the definition of “finance charge.” A class action suit was brought against several banks on behalf of consumers who were charged over-limit fees that were not identified as finance charges. The Sixth Circuit ruled on behalf of the plaintiffs, finding Regulation Z contrary to the plain meaning of the statute.

Justice Thomas on behalf of a unanimous Court applied the familiar test of *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984). The Court focused on the phrase “incident to the extension of credit,” because only if the over-limit fee is assessed “incident to the extension of credit” does it come within the definition of finance charge. While the phrase clearly indicates some necessary connection between the antecedent and its object, “it does not make clear whether a substantial (as opposed to a remote) connection is required.” Consequently, the Court said, the term standing alone is ambiguous. Because it is ambiguous, the Board’s regulation interpreting it “is binding in the courts unless procedurally defective, arbitrary and capricious in substance, or manifestly contrary to statute,” citing *United States v. Mead Corp.*, 533 U.S. 218 (2001). *Chevron* aficionados will note that the description of the *Chevron* second step here does not use the word “permissible” or “reasonable” as the touchstone for upholding the agency interpretation, but rather reiterates the substantive bases in Section 706 of the APA for overturning agency action. Applying that test, however, the Court reverted to form and concluded simply that because over-limit fees “can reasonably be characterized as a penalty for defaulting on the credit agreement, the Board’s decision to exclude them from the term ‘finance charge’ is surely reasonable.”

For almost 50 years, until it was repealed in 1964, the Pittman Underground Water Act authorized the Secretary of Interior to designate certain non-mineral lands in Nevada where settlers could drill for water. Any “valuable minerals” on those lands, however, were reserved to the United States. When the Act was

repealed, it preserved the rights of the then existing patentees. A successor in interest to one of these patentees wished to mine the land for sand and gravel to be used in construction. The Bureau of Land Management, however, held that sand and gravel were valuable minerals reserved to the United States, and this determination was upheld on administrative appeal by the Interior Board of Land Appeals. Nonetheless, the owner sold the rights to BedRoc Limited, which brought a quiet title action in federal district court. In *BedRoc Limited, LLC. v. United States*, 124 S. Ct. 1587 (2004), the Court held for the private owner against the government.

The major issue in the case was the precedent of *Watt v. Western Nuclear, Inc.*, 462 U.S. 36 (1983), in which the Court construed the Stock-Raising Homestead Act of 1916 to include sand and gravel within the terms “coal and other minerals” that were reserved to the United States. That decision split the Court 5-4, with Justices Rehnquist, O’Connor, Stevens, and Powell dissenting. In *BedRoc*, the Court was also split, with no majority opinion. Now-Chief Justice Rehnquist, joined by Justices O’Connor, Scalia, and Kennedy, “share[d] the concerns expressed in the *Western Nuclear* dissent” but concluded it was unnecessary to overrule that decision, because the Pittman Act included the limiting adjective “valuable” to describe the minerals reserved. “Common sense tells us” that no one would have imagined sand and gravel to be valuable minerals in 1918, when the Pittman Act was passed. Accordingly, it was unnecessary to review the legislative history of the Act.

Five justices, however, believed that the terms “minerals” in the SRHA and “valuable minerals” in the Pittman Act had to be interpreted to mean the same thing. But these five could not agree as to what that meaning is. Three justices, Stevens, Souter, and Ginsburg, would follow *Western Nuclear* to include sand and gravel within “valuable minerals.” Two justices, Breyer and Thomas, providing the swing votes for the judgment, took a novel tack on the use of precedent. They believed that “minerals” and “valuable minerals” in the two different acts had no different meaning and had to be construed in the same way. Nevertheless, they believed that *Western Nuclear* was wrongly decided – that “minerals” in the SRHA did not include sand and gravel and accordingly “valuable minerals” in the Pittman Act also did not include sand and gravel. Because, however, “*stare decisis* concerns are at their acme in cases” of statutory interpretation affecting contract or property rights, they would not overrule *Western Nuclear*; instead they would simply not follow it.

Administrative lawyers will note that nowhere in any of the opinions is there any reliance on the agency’s interpretation of the statute, which apparently consistently since 1929 had been to consider sand and gravel both “minerals” and “valuable minerals” in numerous formal adjudications as well as one specifically involving the property at issue here.

What was in the opinions, however, was a little give-and-take on the appropriateness of using legislative history. Justice Stevens quoted a justice of the Supreme Court of Israel for the proposition that judges who will not stray from the language of a statute

retain more discretion in their interpretation than those judges who will look to other sources of meaning as well. This seems like a double dig at Justice Scalia, first by claiming that the use of legislative history actually constrains judges more than its non-use, and second by citing a foreign judge as the source for the quote. In any case, it provoked a footnote response from the Chief Justice (or was it Justice Scalia's ghostwriting?) to the effect that reliance on legislative history in the absence of statutory ambiguity would "require a radical abandonment of our long-standing precedents," citing John Marshall and *Caminetti v. United States*, 242 U.S. 470 (1917) (interpreting the White Slave Traffic Act to reach a man bringing a woman across a state line with the intent that she would become his mistress). He did not address why a statutory provision whose meaning split the Court 4-3-2 was not ambiguous.

Nixon v. Missouri Municipal League, 124 S.Ct. 1555 (2004), is another administrative law case without any administrative law. The Telecommunications Act of 1996 bars any state or local law that prohibits the ability of "any entity" to provide telecommunications services. It places the enforcement authority for this provision not in the courts, but in the Federal Communications Commission, providing that after notice and comment, if the Commission determines that a state or local government has violated this prohibition, the Commission shall preempt the enforcement of the state or local law.

The issue raised in *Nixon* was whether the term "any entity" includes state or local subdivisions, typically publicly owned utilities. If so, the statute would limit the power of states to organize their own internal structures by forcing them to allow publicly owned utilities to provide telecommunications services. The FCC in a series of cases under the provision had held that "any entity" did not include state and local subdivisions, because that term did not satisfy the test of *Gregory v. Ashcroft*, 501 U.S. 452 (1991), that Congress must clearly indicate its intent to affect the ability of states to structure their own organization of government. The Eighth Circuit, acknowledging both *Gregory* and *Chevron v. NRDC*, found the term "any entity" absolutely clear – it meant any entity, which would include state and local subdivisions.

The Supreme Court in an opinion by Justice Souter did not find the term "any entity" absolutely clear, noting that in various places in federal statutes the term entity sometimes is used to include state and local government and sometimes used in a way that excludes them. Consequently, the Court said that "[t]o get at Congress's understanding, what is needed is a broader frame of reference." The broader frame of reference the Court used was to assume the bar did reach state and local subdivisions and then to apply it to a series of hypothetical situations. The result was that, depending upon precisely how a publicly owned utility was created and structured, the utility might or might not actually be allowed to engage in telecommunication activities. The fact

that different results would turn on peculiarities of local government structure, rather than any consistent policy, convinced the Court that to include state and local subdivisions within the term "any entity" held a "promise of futility and uncertainty."

Justice Scalia, joined by Justice Thomas, concurred in the judgment. In their view, the majority went beyond the facts of the case, which dealt only with a political subdivision of a state, not a locality, and they would have limited the analysis to the simple conclusion that *Gregory v. Ashcroft's* requirement was not satisfied.

Justice Stevens dissented. Everyone agreed that Congress intended its ban on state and local governments' control over entry into the telecommunication services to benefit utilities. Justice Stevens believed that it would be incredible for Congress to have intended that protection to apply only to investor-owned utilities and not to publicly owned utilities. Nothing in the legislative history suggests any intent to limit the field of utilities covered by the protections of the Act.

Again, no one attributed any significance to the fact that the FCC had consistently reached the conclusion that "any entity" did not include publicly owned utilities. One might have imagined that once the Court found the term "any entity" unclear, rather than look to a "broader reference," it might have looked to the agency interpretation made in a proceeding clearly intended by Congress to have legal effect. The explanation may lie in the fact that the FCC, while it interpreted the statute not to protect state and local subdivisions, and decided the cases according to that conclusion, contemporaneously announced that it objected to that legal conclusion on policy grounds. That is, rather than interpret the statute consistent with its policy inclination – allowing publicly owned utilities to enter the telecommunications market would increase competition – the agency interpreted the Act according to legal canons – specifically, the rule of *Gregory v. Ashcroft*. In that sense, the agency was not making law pursuant to a congressional delegation in an area of ambiguity, the hallmarks for the applicability of *Chevron* deference.

If *BedRoc* and *Nixon* are administrative law cases without any administrative law, *United States v. Flores-Montano*, 124 S.Ct. 1582 (2004), is a criminal case with an administrative law tail. *Flores-Montano* involved a border search that included disassembling the gas tank of vehicle to find drugs. The Ninth Circuit held that such an intrusive search required reasonable suspicion. The Supreme Court unanimously reversed, holding that the government's authority to conduct suspicionless border searches included the search here. Justice Breyer, however, added a three sentence concurrence: "I join the Court's opinion in full. I also note that Customs keeps track of the border searches its agents conduct, including the

reasons for the searches. This administrative process should help minimize concerns that gas tank searches might be undertaken in an abusive manner.”

Is this an invitation to law enforcement to create administrative systems governing searches or other police practices as evidence of the reasonableness of a search or practice thereunder? This would not be a novel idea, see Anthony Amsterdam, *Perspectives on the Fourth Amendment*, 58 MINN.L.REV. 349(1974), but it is a novel invitation, if that is what it is.

Another non-administrative law case with an administrative law twist is *South Florida Water Management District v. Miccosukee Tribe of Indians*, 124 S.Ct. 1537 (2004). This is a citizen suit brought under the Clean Water Act by an Indian tribe and environmentalists seeking an injunction against the pumping of polluted water from a developed area in south Florida into the Everglades. This pumping is done to avoid natural flooding of the developed area. The Act prohibits the “discharge of a pollutant” into a navigable water without a permit, and “discharge of a pollutant” is defined as “any addition of any pollutant to navigable waters from a point source.” The SFWMD argued that, because the water it is pumping into the Everglades is already polluted, it was merely transporting already polluted waters, not adding pollution to water. The Court quickly and unanimously rejected this argument. Under this theory, even a publicly owned sewage treatment works would not be regulated by the CWA, because the sewage treatment works does not add pollutants to the sewer water, it merely transports them from the sewers to the nation’s waters.

The United States, as amicus curiae, made a different argument: that the words “any addition of any pollutant to navigable waters” means that only additions of pollutants from outside of navigable waters is regulated. Here, the water being pumped into the Everglades is from already polluted “navigable waters,” so while the pumping may add polluted waters to the Everglades water, it is also taking it out of other navigable waters, so there is no overall addition. This “unitary waters” argument suggests the CWA does not regulate the movement of pollution from one navigable water to another. While the Court indicated a certain amount of skepticism with this argument, it did not rule on it, saying it had not been raised in the cert. petition or below. Nevertheless, what the Court did say and did not say about the government’s amicus brief was notable. First, the government argued that the Court should show deference to “a longstanding EPA view” that transporting navigable waters from one place to another cannot constitute the addition of pollutants. However, the Court indicated that the government could not identify any EPA document espousing that view, and an amicus brief on behalf of former EPA administrators identified at least one EPA document taking the opposite view. One wonders how the government can argue “a longstand-

ing agency view” without any evidence of the same. Second, the Court nowhere suggested that the government’s amicus brief itself might be entitled to deference. In *Auer v. Robbins*, 519 U.S. 452 (1997), in an opinion by Justice Scalia, the Court granted *Seminole Rock* deference to an agency interpretation of its own regulation that was contained in an amicus brief. Here, the amicus brief interprets the statute, rather than a regulation and hence would not be entitled to *Seminole Rock* deference, but there are those who might argue it was subject to *Chevron* or at least *Skidmore* deference.

Ultimately, the Court remanded the case to develop the factual record as to whether the waters being pumped into the Everglades as well as the waters already in the Everglades were actually all the same waters, or whether they were two separable navigable waters. If the lower court finds the former to be the case, then all the parties were agreed no permit was required, but if the lower court found the latter to be the case, then the Court said the lower court could then consider the government’s “unitary waters” theory.

The Freedom of Information Act made its way to the Supreme Court this term with the case involving the death scene photos of Vincent Foster’s body, *National Archives and Records Administration v. Favish*, 124 S.Ct. 1570 (2004). The government had denied the FOIA request pursuant to exemption 7(c) – “records or information compiled for law enforcement purposes” if their production “could reasonably be expected to constitute an unwarranted invasion of privacy.” Everyone agreed these were law enforcement records, and all the lower courts had agreed that the privacy interests protected could include those of surviving family members with respect to records or documents concerning their deceased loved ones. The Supreme Court joined the lower courts to confirm that privacy interests are not limited to those of the person to whom the record or document related.

This left the issue that led to the case going to the Supreme Court – balancing the privacy interest of the family against the interest in disclosure. Clearly, the family’s privacy interests were very strong. Here, the plaintiff’s purported interest was to discover government wrongdoing, the disclosure of which is a principal purpose of the FOIA, and therefore also arguably a very strong interest. The Court unanimously held that under the facts of this case the privacy interests outweighed the disclosure interests. In so holding, the Court floated a test to establish “some stability.” “Otherwise, courts [would] be left to balance in an ad hoc manner with little or no real guidance.” First, where there is a protected privacy interest, the requester “must establish more than a bare suspicion” of wrongdoing. Rather, the requester “must produce evidence that would warrant a belief by a reasonable person that the alleged Government impropriety might have occurred.” ○

By William S. Jordan III¹

Ninth Circuit Surveys Administrative Law in Rejecting Ashcroft's Attempt to Stifle Oregon's Death With Dignity Act.

In response to Oregon's Death With Dignity Act, Attorney General Ashcroft issued an informal statement – the “Ashcroft Directive” – declaring that the use of prescription drugs in physician assisted suicide violates the Controlled Substances Act of 1970 (the “CSA”). The Ninth Circuit, over a vigorous dissent, held that the Ashcroft Directive itself violated the CSA. *Oregon v. Ashcroft*, 2004 WL 1162238 (May 26, 2004). The opinions address a wide range of administrative law issues, from reviewability to deference to federalism and principles of statutory construction.

Although an informal statement, the Ashcroft Directive was final under a specific CSA provision rendering “All final determinations, findings, and conclusions of the Attorney General under this subchapter . . . final and conclusive,” 21 U.S.C. 877. It was ripe for review because it presented health care practitioners with a choice between compliance and facing serious criminal penalties. While the majority dismissed these issues with little discussion, the dissent, agreeing that the matter was reviewable, explained at length why this informal statement constituted a reviewable “final determination.” Despite not having the “force of law,” the statement met the two prongs of *Bennett v. Spear* ((1) consummation of the agency decision making process and (2) determination of rights, obligations, or legal consequences) and the principles of *National Automatic Laundry and Cleaning Council v. Shultz*, among other decisions. Contrary to the initial District Court ruling, the agency did not have to seek comment or develop a record in order to produce a “final” decision.

Addressing an issue ignored by the majority, the dissent provides a learned discussion of why the Ashcroft Directive did not violate the APA requirements for notice and comment. As an interpretive statement, the Directive was exempt from those requirements unless it imposed new obligations. But “like other interpretive rules,” the Directive was “‘essentially hortatory and instructional,’ clarifying what the Controlled Substances Act means when applied to a narrowly defined situation.” The fact that the Ashcroft Directive reversed a prior statement issued by Attorney General Reno was irrelevant since the new Directive did not purport to change a position taken in a legislative rule. Notice that this position conflicts with the position of the D.C. Circuit on agency use of informal statements to revise previously issued informal interpretations. See, e.g., *Alaska Professional Hunters Ass'n, Inc. v. FAA*, 177 F.3d 1030 (1999).

The majority and dissent lock horns on the interpretation of the Controlled Substances Act. The majority quickly holds that the Directive violates the plain language and legislative

history of the CSA. Given that holding, it dismisses *Chevron* deference. It also dismisses *Skidmore* deference on the ground that the Attorney General does not have the expertise necessary to support it. Then it refuses to defer to the Directive's interpretation of the relevant regulation on the ground that the interpretation conflicts with an earlier Supreme Court decision. Having avoided deference, the majority then raised the bar for the Attorney General by citing *Solid Waste Agency of N. Cook County v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 172-74 (2001), as dictating that there must be “clear authority” from Congress to support an agency interpretation that intrudes on state authority.

By contrast, the dissent fairly easily finds support for the Ashcroft Directive in the statute and related materials. As to deference, it argues that *Skidmore* deference can apply to the statutory interpretation despite the fact that the agency has changed its position, but the dissent ultimately takes the position that the dispute centers on an interpretation of a regulation. That interpretation is entitled to a highly deferential standard of review (“controlling weight unless it is plainly erroneous or inconsistent with the regulation,” citing *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994)).

D.C. Circuit: No Agency Subdelegation to States Without Express Congressional Authorization.

The FCC's protracted effort to implement the Telecommunications Act of 1996 suffered another setback in *United States Telecom Association v. FCC*, 359 F.3d 554 (D.C. Cir. 2004). This was the FCC's third attempt to direct local telephone companies to “unbundle” services in a way that would allow access by other telephone companies in order to achieve a competitive market for telecommunications services. The courts had remanded previous FCC unbundling rules on the ground that they did not allow decision making that was sufficiently nuanced to take into account varying market conditions. In particular, the courts had established that the FCC's mandate was not to eliminate all barriers to entry. Rather, its role was to eliminate barriers over and above those of a normal competitive market. The FCC's most recent effort addressed some specific considerations and sought to address the problem of wide market variations by delegating substantial decision making authority to state regulatory commissions. The rule granted broad authority to the states to identify the relevant markets and to determine when a market was sufficiently “impaired” to require unbundling of various services.

The D.C. Circuit rejected the proposition that delegation to the states was comparable to delegation to subordinates within the agency. While there is a presumption of authority to delegate to subordinates within an agency, the court stated that an agency “may not sub delegate to outside entities – private or sovereign – absent affirmative evidence of authority to do so.” The court emphasized two theoretical reasons for this rule. First, delegation outside the agency undermines democratic accountability.

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Second, delegation outside the agency “aggravates the risk of policy drift inherent in any principal-agent relationship.”

This is not to say that agencies may not give states important roles in implementing federal programs. The court distinguished three such situations. First, an agency may condition federal approval on an applicant’s obtaining appropriate local or state permits. This recognizes legitimate local concerns. Second, an agency may rely upon an outside entity, such as a state or a private contractor, to gather factual information. Third, an agency may seek advice from outside entities as long as it makes the ultimate decision itself. In the case at hand, the delegation to state regulatory bodies went well beyond any of these three situations.

As the FCC’s attempt to address market variations, the delegation to the states was the lynchpin of its new unbundling rule. Having rejected that “safety valve,” the court then held the remainder of the rule arbitrary and capricious for failure to explain the rejection of various proffered alternatives. As to the standard of review, the court said, “. . . a rule is irrational in this context if a party has presented to the agency a narrower alternative that has all the same advantages and fewer disadvantages, and the agency has not articulated any reasonable explanation for rejecting the proposed alternative.”

Of several other rulings both for and against the Commission, two are worth mention. First, the court held that the National Association of State Utility Consumers Advocates (“NASUCA”) did not qualify for associational standing to represent the interests of electric consumers. The NASUCA is a non-profit organization of state consumer advocates that have been designated by the state to represent the interests of utility consumers. Without explanation of the governing principles, the court simply held that the record did not demonstrate that the NASUCA qualified for associational standing as a non-membership association. The cited decisions, however, establish that a non-membership organization may assert associational standing if “the organization is the functional equivalent of a traditional membership organization.” Such an organization would qualify if (1) it served a specialized segment of the community, (2) those whom it served were effectively members in the sense of electing officials and financing operations, and (3) the fortunes of the organization were closely tied to the fortunes of those whom they purported to represent. *Fund Democracy, LLC v. SEC*, 278 F.3d 21, 25–26 (D.C. Cir. 2002) (discussing the test in greater detail). The NASUCA probably failed that test because it was not shown that consumers were effectively, if not legally, members of the organization.

Finally, the court dismissed state claims that the FCC improperly sought to preempt certain state unbundling requirements. These claims were not yet ripe because the FCC rule provided a mechanism by which to seek an FCC ruling on whether the new rule preempted particular state requirements. The fact that the FCC had said that such state requirements were “unlikely” to be found consistent with the Act was not enough to render the FCC’s rule ripe for review on this issue.

Chevron – Refining the Mead Test for Application of Chevron Deference, and Articulating the Nature of Chevron Reasonableness Review.

In *Chevron*, the Court identified two distinct bases for strong deference to agency statutory interpretation, with two seemingly distinct standards of review. First, if Congress explicitly delegates the authority to “elucidate a specific provision of the statute by regulation,” the regulatory interpretation will control “unless [it is] arbitrary, capricious, or manifestly contrary to the statute.” Second, if Congress implicitly delegates interpretive authority (by using ambiguous language), the agency’s interpretation must be accepted if it is reasonable.

U.S. v. Mead later held that *Chevron* deference is available only if Congress has delegated the authority to issue the interpretation with the force of law, and if the agency has promulgated the interpretation in the exercise of that authority. The Customs interpretation in *Mead* failed the second prong of that test. Having been issued by a local office, even though also stated by higher Customs authority, it did not derive from the exercise of delegated interpretive authority.

In *Pharmaceutical Research and Manufacturers of America v. Thompson*, 362 F.3d 817 (D.C. Cir. 2004), the D.C. Circuit upheld HHS approval of a Michigan drug-rebate program alleged to violate the Medicaid legislation. Relying upon *Mead*, the challengers argued that the relevant statutory interpretations were not entitled to *Chevron* deference because they were “not the result of a formal administrative process, [did] not involve agency expertise, [were] inconsistent with previous HHS interpretations and were developed solely in response to this lawsuit.” But *Mead* explicitly left open the possibility that *Chevron* deference might apply in the absence of relatively formal procedures. Unfortunately, *Mead* provided little guidance as to when *Chevron* deference would apply in the absence of such procedures. *Pharmaceutical Research* helps to clarify this point. In this case, *Chevron* deference apparently applied because Congress had delegated decisional authority that necessarily involved resolving interpretive questions in approving a state program. It is noteworthy that the court also mentioned, albeit in a footnote, the fact the Customs decisions in *Mead*, reached in thousands of cases by 49 offices, were not meant to affect third parties, while HHS sought to implement a uniform policy with respect to the fifty state Medicaid programs. Ultimately, the question is whether, given all the facts and circumstances, Congress would have intended highly deferential review of the particular interpretation.

Pharmaceutical Research is interesting for a separate *Chevron*-related reason. Apparently distinguishing *Mead* as having involved an implicit delegation, the court found that the statutory mandate to approve state Medicaid plans constituted an “express delegation” of specific interpretive authority. It is not entirely clear whether the court intended to characterize the delegation as “explicit” in the *Chevron* sense, and thus

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subject to review as “arbitrary, capricious, or manifestly contrary to the statute.” It seems equally likely that the court meant that the delegation was strong enough to meet the *Mead* threshold for *Chevron* reasonableness review despite the absence of formal procedures. This raises the question of whether there is any difference between the standards of review for explicit or implicit delegations of interpretive authority, and the broader question of whether there is a difference between arbitrary and capricious review and *Chevron* reasonableness review.

Sierra Club v. Leavitt, 2004 WL 955357 (May 5, 2004), suggests there is no difference between the two standards of review. In another cooperative federalism case, the Sierra Club challenged EPA’s approval of Georgia’s approval of a Clean Air Act preconstruction permit for a new power plant. Both the Clean Air Act and a Georgia rule dictated that such a preconstruction permit could be issued only if all of the other “major stationary sources owned or operated” by the applicant complied with the Act. The applicant owned two complying units of another “major stationary source.” Although those units complied, the source as a whole did not. Thus, the Sierra Club claimed a violation of the statute and the Georgia rule.

Mixing standards of review, the Eleventh Circuit said, “When the CAA or its implementing regulations are ambiguous, we defer to the EPA’s reasonable interpretation. (Citing *Chevron*) However, it would not be appropriate to defer to EPA’s interpretation at this time because in reaching its interpretation, EPA failed entirely to address or explain part of the problem it faced. (Citing *State Farm*).” The court also cited a Second Circuit decision for the proposition that arbitrary and capricious review is “functionally equivalent” to *Chevron* reasonableness review. On the facts of the case, the court refused to defer because EPA had failed to explain how it could use the term “major stationary source” to refer to a multi-unit facility in some instances, but then allow the term to refer to only two units of such a facility in this case.

FOIA – DC Circuit Addresses the Scope of Protection for Congressional and Presidential Communications.

Neither Congress nor the President is subject to the Freedom of Information Act, but records generated by or closely related to those bodies frequently end up in agencies that are subject to FOIA. When such records are sought in a FOIA request, two questions arise: (1) whether, since they are physically located within the agency, these constitute agency records, and (2) whether, assuming they are agency records, they are nonetheless exempt from disclosure for some reason.

In *United We Stand America, Inc. v. IRS*, 359 F.3d 595 (D.C. Cir. 2004), the D.C. Circuit, over a vigorous dissent, held that an IRS report prepared in response to a congressional request was a disclosable agency record, except that any parts of the report that

would reveal the congressional request were not subject to disclosure. The report had been prepared by the IRS in response to a letter from the Joint Committee on Taxation. The Joint Committee’s letter stated that it was a Congressional document, not subject to release without approval. In response to an FOIA request covering the report, the IRS justified nondisclosure on the ground that the IRS had not used the report for its own purposes, that it had kept the report in a separate file as a congressional document, and that release of the report would effectively constitute release of the Joint Committee’s letter, which was clearly not an agency record.

Noting that congressional involvement distinguished this case from the Supreme Court’s decision in *Tax Analysts*, the court stated the four-part test that the D.C. Circuit had developed to determine whether a document is an agency record: “(1) the intent of the document’s creator to retain or relinquish control over the records; (2) the ability of the agency to use and dispose of the record as it sees fit; (3) the extent to which agency personnel have read or relied upon the document; and (4) the degree to which the document was integrated into the agency’s record system or files.” The key to this case is the underpinnings of the second factor, “the agency’s ability to use or dispose of the record as it sees fit.” Ultimately, the court held that the outcome turned “on whether Congress manifested a clear intent to control the document.” Applying those principles to the facts, the court held that the report was subject to disclosure except to the extent that it might reveal the original congressional request. In the absence of a “clear” expression of congressional intent to control the report as well as the original request, agency filing and other handling of the document could not protect what would otherwise be a standard agency record.

Judge Henderson dissented on two grounds. First, she argued that the majority had improperly ignored the other three factors of the applicable test, all of which favored the conclusion that this was not an agency record. Second, she argued that it is not possible to divide a particular document into record and non-record material. Either the entire document qualifies as an agency record, or none of it does. Violating that principle, she said, the majority had effectively created a new exemption to those stated in 5 USC 552(b). The requirement to release “any reasonably segregable portion of a record” applies only once it is established that a document is an agency record. The concept cannot be used to divide a single document into record and non-record material.

Turning to the question of Presidential materials, the D.C. Circuit in *Judicial Watch, Inc. v. Department of Justice*, 365 F.3d 1108 (D.C. Cir., 2004), protected some but not all of the materials at issue, and again prompted a strong dissent that would have protected all of them. *Judicial Watch* had sought any and all pardon grants by President Clinton and any and all pardon applications considered by President Clinton. Although the Department of Justice released thousands of pages of documents, it withheld 4,341 pages under both Exemption 5 (deliberative

process privilege) and Exemption 6 (to the extent of protectable personal information), and 524 pages under Exemption 6.

DOJ also asserted that all but the latter 524 pages fall under presidential communications privilege, which it argued protects all documents generated in the course of preparing pardon recommendations for the President. DOJ based this argument on the proposition that the Pardon Attorney works only on matters related to presidential consideration of pardon requests. Since the pardon power is a non-delegable presidential power, the Pardon Attorney is effectively working for the President, despite being located in the Department of Justice.

The majority disagreed, limiting the presidential privilege to documents “solicited and received” by the President or his “immediate White House advisers who have ‘broad and significant responsibility for investigating and formulating the advice to be given the President.’” The decision is striking for two reasons. First, the court is prepared to distinguish among the President’s advisers. It is only “immediate” advisers with “broad and significant responsibility” whose communications would be privileged. Second, the court explicitly holds the President responsible for the choice of where in government to locate certain advisers. Because government structure is significant to the application of FOIA, a President’s decisions about location of advisers is considered to reflect an understanding of differing status as to confidentiality. Note that although the presidential communications privilege might not apply to some of the records at issue, DOJ could still seek to rely on the deliberative process privilege.

Somewhat ironically, Judge Henderson, who dissented in *United We Stand*, joined the majority, while Judge Randolph dissented. Judge Randolph would have protected all of the work of the Patent Attorney. He argued for a clear and unmistakable dividing line, “distinguishing advice about ‘a quintessential and nondelegable Presidential power,’ which is subject to the privilege, from ‘information regarding governmental operations that do not call ultimately for direct decision-making by the President,’ which is not.”

Potpourri – Attorney Discipline, Standing, Defense to Civil Penalty, and *res judicata* Effect of State Administrative Decisions.

Several other recent decisions deserve brief mention. As to attorney discipline, the Ninth Circuit rejected an argument that the California Supreme Court had no jurisdiction to discipline an attorney who practiced solely before the INS and the federal courts. In *Gadda v. Ashcroft*, 363 F.3d 861 (9th Cir. 2004), California disbarred Gadda primarily for his actions before the INS. The Ninth Circuit held that not only was there no federal preemption of state discipline of agency practitioners, federal courts and agencies rely heavily on the states to police members of their bars who practice in the federal arena.

As to standing, the nation’s collegiate wrestling coaches and athletes suffered a takedown in their attempt to challenge a

policy statement setting out a three-part test to determine the application of Title IX’s prohibition on sex discrimination in collegiate athletics. The challengers argued that the policy statement’s focus on judging equal opportunity based upon student enrollment, rather than upon student interest in sports, violated earlier regulations, the statute, and equal protection. In *National Wrestling Coaches Ass’n v. Department of Education*, 2004 WL 1073836 (May 14, 2004), the D.C. Circuit held that the wrestlers could not meet the redressability prong of standing because the educational institutions might cut their teams to meet the earlier regulation, regardless of the policy statement. The proposition that rejection of the policy statement would produce “better odds” that men’s wrestling teams would be maintained was not enough to constitute redressability. Judge Williams dissented, emphasizing that government action need not control the outcome in order to meet the redressability prong. Rather, all that is needed, he said, is that government action be a “substantial factor” influencing outcomes. He argued that the wrestlers had made a sufficient factual showing to meet that test.

In *Delta Commercial Fisheries Association v. Gulf of Mexico Fishery Management Council*, 364 F.3d 269 (5th Cir. 2004), commercial fisheries lacked standing in their challenge to the make up of the local Fishery Management Council, which was responsible for regulating fishing in the Gulf of Mexico. The commercial fisheries complained that the membership of the Council was unfairly weighted toward recreational fishing interests, in violation of the statutory requirement that membership be “fair and balanced.” According to the Fifth Circuit, the assertion that unbalanced membership would harm the livelihood of commercial fishermen was not sufficient to support standing. Without complaining of the effects of a specific plan, order, or enforcement action, the commercial fisheries showed nothing more than a generalized interest in the proper application of law, not enough to constitute the required particularized injury in fact.

In a case that may have ramifications in other enforcement arenas, the Third Circuit recognized a “laboratory error” defense to a Clean Water Act violation based upon the company’s reported discharges. The court also provided an extensive and useful discussion of principles governing the determination of civil penalties. *U.S. v. Allegheny Ludlum Corp.*, 366 F.3d 164 (3d Cir. 2004) involved an appeal of an \$8 million civil penalty. The company argued that some of the violations should be excused because they were based solely upon erroneous figures reported by the company. The unduly high figures were the result of use of a contaminated reagent in the laboratory process. While the government emphasized the need to hold the company strictly liable for its reports in order to avoid extensive litigation about the figures company reports, the court distinguished between reporting violations and violations of discharge limits. As to the latter, the court noted that strict liability eliminates the mens rea, but not the actus reus. The government must show that the discharge violation actually happened, and a company may seek to

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Recent Articles of Interest

By Yvette M. Barksdale¹

1. Peter M. Shane, *WHEN INTER-BRANCH NORMS BREAK DOWN: OF ARMS-FOR-HOSTAGES, "ORDERLY SHUTDOWNS," PRESIDENTIAL IMPEACHMENTS, AND JUDICIAL "COUPS,"* 12 *Cornell Journal of Law and Public Policy* 503 (2003).

In this article, Peter Shane argues that actions by the three branches of government over the last 20 years have seriously weakened the basic tripartite constitutional structure of the government. These actions violate bedrock foundational "norms" that our government 1) has three interdependent branches with distinct individual roles, and 2) should act in the broad interest of the whole society. Examples include the Iran-Contra scandal in which the executive sought to eliminate Congress's foreign policy role; the 1995 budget shutdown of the executive; the Clinton impeachment which sought to subjugate the President to Congressional control; and the stonewalling of Clinton judges which usurped the President's Appointments power. Professor Shane discusses likely reasons for these attacks on tripartite government, including the ascendancy of "presidentialist" constitutional theory and the evolution of peculiar geographic and other demographic characteristics of the electorate which reduce the ordinary political checks on such actions. Shane also recommends strategies to protect the interbranch structure, including an interbranch bipartisan cease and desist treaty.

2. Jack M. Beermann, *PRESIDENTIAL POWER IN TRANSITIONS,* 83 *B.U. L. Rev.* 947 (2003).

This article makes recommendations regarding "lame-duck" presidential actions which occur in the transition period between the election of a new President and the end of the predecessor's term. Drawing predominantly on examples from the transition between the terms of Presidents Bill Clinton and George W. Bush, the article describes the kinds of actions that the outgoing President might take and possible reactive actions by the incoming administration. The article next discusses possible reforms and concludes that reforms directed to enhancing the ability of incoming administrations to handle "midnight regulations" are likely preferable to those aimed at outgoing administrations. The article also concludes that "midnight regulations" are likely here to stay, but reforms are possible if the phenomenon is viewed as problematic. The article also generally discusses presidential involvement in the administrative process.

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3. Cass R. Sunstein, David Schkade and Lisa Michelle Ellman, *IDEOLOGICAL VOTING ON FEDERAL COURTS OF APPEALS: A PRELIMINARY INVESTIGATION,* 90 *Va. L. Rev.* 301 (2004).

This article summarizes an empirical study of the effects of political ideology on judges' decisions. The study used the political affiliation of the appointing President (Democrat or Republican) as a proxy for the judge's political ideology. The study examined post-1995 federal Courts of Appeals judicial decisions in thirteen ideologically controversial subject matters ranging from abortion to takings.

The authors found that in most of these subject areas, 1) the political party of the appointing president is a fairly good predictor of how an individual judge will vote, and 2) an individual judge's vote is at least as equally well predicted by the political party of the other two panelists' appointing President. Thus an individual judge, regardless of political affiliation, was more likely to vote conservative when the other two panelists were Republican appointees, than when the other panelists were Democratic appointees. Democratic appointed judges were somewhat more susceptible to these "panel effects" than were Republican appointed ones.

However in criminal appeals, takings claims, and Commerce Clause challenges to congressional enactments, ideology did NOT predict the votes of individual judges or panels. In abortion and capital punishment cases, ideology DID predict an individual judge's votes, but the ideology of the other panelists did not matter.

The authors concluded that these panel composition effects create serious problems for the rule of law, since litigants' chances were significantly affected by the luck of the draw. The study also found the Ninth, Third, and Second Circuits the most liberal; the Fifth and Seventh the most conservative.

4. Arthur D. Hellman, *ESSAY ASSESSING JUDGESHIP NEEDS IN THE FEDERAL COURTS OF APPEALS: POLICY CHOICES AND PROCESS CONCERNS,* 5 *Journal of Appellate Practice and Process* 239 (2003).

The author discusses the March 2003 recommendation of the Judicial Conference of the United States that Congress create eleven new judgeships for the federal Courts of Appeals. The author agrees these judgeships are sorely needed given the circuits' substantially increased caseloads. However, he questions 1) why the Judicial Conference did not recommend new positions for the Fifth and Eleventh Circuits which had the largest caseloads by the Judicial Conference's own measure, and 2) whether the Judicial Conference's process for formulating recommendations provides Congress sufficient information to make sound judgeship creation decisions. The

author wishes 1) to promote informed debate among the Fifth and Eleventh Circuit judges and lawyers regarding these two Circuits' policies for handling increased caseloads, and 2) to persuade the Judicial Conference that opening up its process for assessing judgeship needs will give Congress a wider range of information, including non-quantitative information, and will benefit both Congress and the Judiciary.

5. Julius Getman, *THE NATIONAL LABOR RELATIONS ACT: WHAT WENT WRONG; CAN WE FIX IT?*, 45 B.C. L. Rev. 125 (2003).

The author analyzes why the National Labor Relation Act (NLRA), initially enacted to facilitate unionization and collective bargaining, no longer protects workers or collective bargaining. The author blames 1) the continuing role of the judiciary (a role not contemplated at the legislation's enactment), 2) the continued pernicious influence of common law concepts, 3) the equivocal performance of a politicized National Labor Relations Board (NLRB) which has supplied neither expertise, clear doctrine, nor consistency and 4) the increasing role of state law and of arbitration agreements, combined with the reduction of collective bargaining and the "right to strike." The author proposes several specific legislative amendments to the NLRA to better and more evenhandedly protect workers' rights.

6. David E. Adelman, *SCIENTIFIC ACTIVISM AND RESTRAINT: THE INTERPLAY OF STATISTICS, JUDGMENT, AND PROCEDURE IN ENVIRONMENTAL LAW*, 79 Notre Dame L. Rev. 497 (2004).

This article evaluates how scientific judgment is shaped by scientific methods, particularly the choice of statistical techniques. The Article thoroughly describes the analytical and historical foundations of the two principal statistical theories: 1) "frequentism," which relies upon rigorous testing, objective frequencies, and measures of statistical significance, and 2) "Bayesianism," which uses scientific knowledge to interpret experimental results based upon direct probabilities, subjective judgments, and logic. The author discusses the fundamental legal and scientific debates about the proper role of science during three analytical stages: (1) reducing experimental information to quantitative results; (2) drawing inferences from discrete scientific studies; and (3) integrating results from multiple experimental studies to set environmental policy. For each stage, the author advocates policies or procedures to mitigate flaws in both Bayesian and frequentist methods, and to expand options available to guide judgment in environmental policy. The author advocates deeper appreciation by lawyers and policymakers for the limits and strengths of scientific methods.

7. Alex Geisinger, *A GROUP IDENTITY THEORY OF SOCIAL NORMS AND ITS IMPLICATIONS*, 78 Tul. L. Rev. 605 (2003).

This article critiques recent law and economics social norms scholarship. Social norms are behavioral rules supported by a pattern of informal sanctions. Some social norm advocates argue that such private norms are preferable to law because they efficiently aggregate individual private choices and thus sidestep collective action and other problems of government action. However, the author is skeptical that social norms can supplement or substitute for law because social norms may not merely aggregate the rational choices of self-interested individuals. Rather, the author argues, social norms are formed by people within groups who have a social, as well as an individual, identity. This group identity may alter individual decisions, and thus the resulting social norms, from those formed purely by aggregating rational self-interested individual choices. If so, regulation by social norms may simply substitute a new set of group-based decision-making problems for the old legislative ones.

8. Spencer Overton, *RESTRAINT AND RESPONSIBILITY: JUDICIAL REVIEW OF CAMPAIGN REFORM*, 61 Wash. & Lee L. Rev. 663 (2004).

In the wake of the Supreme Court's campaign finance decision, *McConnell v. FEC*, 124 S. Ct. 619 (2003), the author argues for increased doctrinal coherence in judicial review of the constitutionality of campaign finance requirements. Otherwise, inadequate doctrinal guidance will compel even the best judges to rely merely on their own assumptions about the role of money in politics when reviewing reforms. This Article uses the controversy in *McConnell v. FEC* to illustrate the challenges that courts face when attempting to distinguish between effective reforms that properly close loopholes and those that intrude excessively on first amendment values. The author then develops a framework to facilitate more principled judicial review. The Article proposes that the Court expressly articulate the values that its doctrine seeks to serve, relying upon precedent which suggests that the Justices should aim to promote four democratic values: democratic deliberation, widespread participation, individual autonomy, and electoral competition. Judges should uphold reforms that, on balance, advance these values. A requirement that judges invalidate regulations that do more harm than good to these four values would provide more normative guidance than the current "substantial overbreadth" doctrine.

9. Jamin B. Raskin, *BOOK REVIEW, THE CAMPAIGN FINANCE CRUCIBLE: IS LAISSEZ FAIR?*, 101 Mich. L. Rev. 1532 (2003), (reviewing: Bradley A. Smith, *UNFREE SPEECH: THE FOLLY OF CAMPAIGN FINANCE REFORM* (Princeton University Press, 2001); and Bruce Ackerman and Ian Ayres, *VOTING WITH DOLLARS: A*

NEW PARADIGM FOR CAMPAIGN FINANCE (Yale University Press 2002).)

Writing before the decision in *McConnell v. FEC*, 124 S. Ct. 619 (2003), reviewer Raskin discusses two campaign finance reform books.

The reviewer describes the first book, *UNFREE SPEECH: THE FOLLY OF CAMPAIGN FINANCE REFORM*, by Bradley Smith (a Federal Elections (FEC) Commissioner), as an eloquent impassioned defense of free market campaign finance. Author Smith debunks the standard rhetorical critiques that money 1) has an inordinate role in politics (Americans spend twice as much money on potato chips), and 2) corrupts politics. However, Smith balks at the implications of his own libertarianism, evading many difficult issues including the role of private corporations in campaign. Ultimately Smith endorses the pre-2002 status quo. The second book, *VOTING WITH DOLLARS: A NEW PARADIGM FOR CAMPAIGN FINANCE*, by law professors Bruce Ackerman and Ian Ayres, is described as an “intriguing and spirited . . . manifesto” for a massive voucher solution to campaign-finance reform. The plan’s central feature is “patriot dollars”, a guaranteed \$50 government subsidy for every American to contribute, anonymously through a government blind trust, to federal campaigns, political action committees, or political advocacy groups. The plan would also raise individual campaign contribution limits as high as \$100,000. The authors’ plan is sweepingly ambitious, gimmicky in parts, and sometimes infected with Bradley Smith’s ideological romance with “markets.” But, the reviewer concludes, the book provides a real alternative to the depressing recent reform cycle of money domination and command-and-control regulation.

Recent Symposia of Interest:

1. SYMPOSIUM, “TECHNOLOGY AND GOVERNANCE: HOW THE INTERNET HAS CHANGED OUR CONCEPTIONS OF GOVERNANCE AND INSTITUTIONS,” **35 LOY. U. CHI. L. J. 1, ET SEQ. (2003)**. **Articles by Lawrence Lessig**, *Law Regulating Code Regulating Law*, p. 1; **James B. Speta**, *FCC Authority to Regulate the Internet: Creating It and Limiting It*, p. 15; **Philip J. Weiser**, *Toward a Next Generation Regulatory Strategy*, p. 41; **Jay P. Kesau**, *Private Internet Governance*, p. 87; **A. Michael Fromkin**, *Commentary: Time to Hug a Bureaucrat*, p. 139; **Justin Hughes**, *Of World Music and Sovereign States, Professors and the Formation of Legal Norms*, p. 155; **Brett M. Fischmann**, *The Prospect Of Reconciling Internet And Cyberspace*, p. 205; **Jaqueline Lipton**, *Mixed Metaphors in Cyberspace: Property in Information and Information Systems*, p. 235; **Michael J. Madison**, *Reconstructing the Software License*, p. 275; and **David McGowan**, *Website Access: The Case for Consent*, p. 341.
2. Symposium, “Science in the Regulatory Process,” Richard Merrill, Special Editor, **66-FALL LAW AND CONTEMP. PROBS. 1, ET. SEQ. (2003)**. Foreword by Richard Merrill,

- p.1; and **Articles by Alan Charles Raul and Julie Zampa Dwyer**, “Regulatory Daubert”: A Proposal To Enhance Judicial Review Of Agency Science By Incorporating Daubert Principles Into Administrative Law, p.7; **E. Donald Elliott**, *Strengthening Science’s Voice at EPA*, p.45; **Wendy E. Wagner**, *The “Bad Science” Fiction: Reclaiming The Debate Over The Role Of Science In Public Health And Environmental Regulation*, p.63; **Jerry L. Mashaw**, *Law and Engineering: In Search of the Law-Science Problem*, p.135; **Thomas O. McGarity**, *On the Prospect of “Daubertizing” Judicial Review of Risk Assessment*, p.155; **Donald T. Hornstein**, *Accounting for Science: The Independence of Public Research in the New, Subterranean Administrative Law*, p.227; and **Bernard D. Goldstein and Russellyn S. Carruth**, *Implications of the Precautionary Principle for Environmental Regulation in the United States: Examples from the Control of Hazardous Air Pollutants in the 1999 Clean Air Act Amendments*, p.247.
3. SYMPOSIUM, “REVISITING THE MECHANISMS OF MARKET EFFICIENCY,” **28 J. OF CORP. LAW 499, ET SEQ. (2003)**. **Donald C. Langevoort**, *Foreword: Revisiting Gilson and Kraakman’s Efficiency Story*, p. 499; **Allen Ferrell**, *If We Understand the Mechanisms, Why Don’t We Understand Their Output?*, p. 503; **Alon Brav & J. B. Heaton**, *Market Indeterminacy*, p. 517; **Paul G. Mahoney**, *Market Microstructure and Market Efficiency*, p. 541; **William T. Allen**, *Securities Markets as Social Products: The Pretty Efficient Capital Market Hypothesis*, p. 551; **Robert H. Sitkoff**, *Trust Law, Corporate Law, and Capital Market Efficiency*, p. 565; **Saul Levmore**, *Simply Efficient Markets and the Role of Regulation: Lessons from the Iowa Electronic Markets and the Hollywood Stock Exchange*, p. 589; **Herbert Hovenkamp**, *Antitrust Violations in Securities Markets*, p. 607; **Lynn A. Stout**, *The Mechanisms of Market Inefficiency: An Introduction to the New Finance*, p. 635; **Howell Jackson**, *To What Extent Should Individual Investors Rely on the Mechanism of Market Efficiency: A Preliminary Investigation of Dispersion in Investor Returns*, p. 671; **Guhan Subramanian**, *The Drivers of Market Efficiency in Revlon Transactions*, p. 691; **Ronald J. Gilson & Reinier Kraakman**, *The Mechanisms of Market Efficiency Twenty Years Later: The Hindsight Bias*, p. 715.
 4. SYMPOSIUM, “200TH ANNIVERSARY, MARBURY V. MADISON AND JUDICIAL REVIEW: LEGITIMACY, TYRANNY AND DEMOCRACY,” **37 J. MARSHALL L. REV. 317, ET. SEQ. (2004)**. Foreword by **Samuel R. Olken**, p. 317; **Articles by William E. Nelson**, *The Province of the Judiciary*, p. 325; **Larry D. Kramer**, *The Pace and Cause of Change*, p. 357; **Samuel R. Olken**, *The Ironies of Marbury v. Madison and John Marshall’s Judicial Statesmanship*, p. 391; **Louis Michael Seidman**, *The Secret Life of the Political Question Doctrine*, p. 441; **Thomas W. Merrill**, *Marbury v. Madison as the First Great Administrative Law Decision*, p. 481; **Mark Tushnet**, *Constitutional Hardball*, p. 523; **Walter Kendall**, *Reflections on Judicial Review and the Plight of the Poor in A World Where Nothing Works*, p. 555. ○

When Patient Privacy and Medical Law Enforcement Collide

By Michael Asimow¹

Dr. Bearman prescribed marijuana for Nathan's migraines and attention deficit disorder (ADD). Nathan went camping and was caught by a park ranger with marijuana. He showed the ranger Dr. Bearman's letter and the ranger turned it over to the California Medical Board. The Board suspected that Dr. Bearman had abused his power to prescribe marijuana and started an investigation. It subpoenaed Nathan's medical records but Dr. Bearman and Nathan refused to turn over the documents.

Under federal law, there's not much point in fighting an administrative subpoena. An agency can obtain just about any document it wants without a showing of probable cause or relevance. But state law may be different. The Court of Appeal refused to enforce the subpoena because of the patient's right to privacy under the California constitution.

The court ruled that without a showing of probable cause to believe Dr. Bearman had violated the law, the Board could not obtain the documents. Dr. Bearman's letter seemed on its face an appropriate medical decision under California's medical marijuana law (the statute mentions migraines but not ADD treatment as permissible uses). Thus the letter didn't provide probable cause. *Bearman v. Superior Court*, 2004 Cal.App.Lexis 438 (April 1, 2004).

While the *Bearman* decision strikes a blow for patient privacy and prescription of medical marijuana, it is still troubling. Rooting out incompetent or corrupt doctors or other health professionals is a tough job but essential for consumer protection. Is it wise to hobble the Medical Board's ability to obtain patient records when the patient won't consent to producing them? Such records are often the only way to prove a case against a bad doctor (and in California such proof must be by "clear and convincing evidence").

Quintero: On Carrying a Good Thing Too Far

By Michael Asimow

Separation of functions is a good thing, but *Quintero v. City of Santa Ana*, 7 Cal.Rptr.3d 896 (Court of Appeal, 2003) carried it to an extreme. The City sought to fire Quintero, a police detention officer, for having sex with a female officer "while on duty and in uniform." Hugh Halford prosecuted the case before the Personnel Board. On previous occasions, Halford had served as a board adviser. The court thought that "it would be only natural for the board members, who have looked to Halford for advice and guidance, to give more credence to his arguments when deciding plaintiff's case." In other words, the Board members were biased because the prosecutor had served as a Board adviser in other cases.

¹ Professor of Law Emeritus, UCLA Law School; Council Member; and Contributing Editor.

Whether separation of functions is required by state or federal APAs or by due process, it has never before disqualified a staff member because that person carried out inconsistent functions in different cases. The purpose of separation of functions is to prevent an adversary in a case from acting as a judge (or adviser to a judge) in the *same case* because the adversary function creates a will to win that particular case. *Quintero* is like saying that a lawyer who once acted as a clerk for a judge can't take a job with the DA's office and prosecute a case before the same judge because the judge would give undue credence to his arguments.

Quintero creates serious dilemmas for small cities: they must permanently separate their staff members so that advisers in one case cannot be adversaries in another. Yet small cities have tiny legal staffs, each member of which is expected to do whatever job is needed. This sort of separation is completely impracticable. Cities must have flexibility in how they use their staff members. Of course, the City could hire outside lawyers to prosecute cases, but this is a very costly expedient. I, for one, would not enjoy telling the Santa Ana City Council that they must spend \$500 per hour to hire lawyers to prosecute personnel cases before the Personnel Board because the staff members have been disqualified from doing so.

The judges who decided *Quintero* were unaware of the principles of administrative law in general and small-city administrative practice in particular. Unfortunately, the California Supreme Court denied a hearing in *Quintero* and refused to depublish the case (California has an unusual practice of depublishing Court of Appeal opinions that the Supreme Court doesn't like but can't be bothered hearing). Now, trial courts will be required to follow the case, casting doubt on the validity of countless personnel, licensing, or land use decisions by local agencies.

When Is Local Government an "Administrative Agency"? Round One in California's Same Sex Marriage Heavyweight Title Bout

By Marsha Cohen²

California's voters knew, in June 1978, that a ballot measure before them would have repercussions even a quarter-century later – Proposition 13, the property-tax-limiting initiative. But surely no one suspected that Proposition 5 on the same ballot, a constitutional amendment innocently titled, "Administrative Agencies," would fill the California Supreme Court's courtroom to overflowing in 2004.

But it did. The innocent-sounding amendment played the starring role in the first round of the California battle over same-sex marriage. The amendment added to the California Constitution a provision declaring, in pertinent part, that "An administrative agency ... has no power ... [t]o declare a statute unenforceable, or refuse to enforce a statute, on the basis of it being unconstitutional unless an appellate court has made a

² Professor of Law, Hastings College of the Law.

determination that such statute is unconstitutional. . .” (Cal. Const., Art. III, §3.5). As everyone knows, in February 2004 (just in time for Valentine’s Day), San Francisco Mayor Gavin Newsom directed the County Clerk’s Office (San Francisco is a contiguous city/county) to issue marriage licenses to same-sex couples. He argued that refusal to do so was unconstitutional, in light of court decisions in Hawaii, Vermont, and Massachusetts, and supported by the reasoning in the United States Supreme Court’s decision in *Lawrence v. Texas*, 539 U.S. 558 (2003). Prior to the issuance of an order by the California Supreme Court on March 11, 2004, directing the City to enforce the provisions of the California Family Code defining marriage as between a man and a woman “without regard to respondents’ personal view of the constitutionality of such provisions,” more than 3,500 same-sex marriages had been licensed.

The Court’s hearing on May 25, concerning whether a writ of mandate should be granted, was limited to the question whether San Francisco officials have the authority to refuse to enforce California’s marriage statutes in the absence of a judicial determination that they are unconstitutional. Section 3.5 of Article III, which has attracted only scant judicial attention since its passage, was the central concern.

Proposition 5 was placed on the ballot after a California Supreme Court decision involving the state’s Public Utilities Commission, in which the Justices clashed over the authority of the PUC to take action based upon its determination about a statute’s constitutional validity. While it was intended to resolve the debate, its impact on agency behavior is unclear.

The most basic question for the Court is whether Mayor Newsom, the County Clerk, and the City and County of San Francisco itself (and by extension, *all* public officials within the state) are an “administrative agency” covered by section 3.5. The answer will turn, of course, on California local government and administrative law. But the broader picture was reflected in competing hypotheticals in the briefs and at oral argument. The City raised the specter of local officials – whose oath requires them to preserve and defend both California and United States Constitutions – forced to implement a law forbidding Muslim girls from wearing head scarves were an anti-gang statute prohibiting hats or other headgear in public schools to be passed, even if a federal appellate court had held in a similar case from another state that Muslims had a fundamental right to express their religion. A Justice at oral argument asked whether local officials should be allowed to refuse to enforce gun control laws on the grounds of their conflict with the Second Amendment. Both sides recognized that the underlying disputes in these hypotheticals would ultimately be settled by courts, but only after a time delay for that judicial action.

At oral argument no one raised the problem (cited in the City’s briefs) that local and state officials can be caught between Scylla and Charybdis because of section 3.5. The Ninth Circuit, in *LSO, Ltd. v. Stroh*, 205 F.3d 1146 (9th Cir. 2000), refused to accept section 3.5 as an excuse for the California Department of

Alcoholic Beverage Control to violate federal constitutional rights of licensees, citing the Supremacy Clause: “It is a long-standing principle that a state may not immunize its officials from the requirements of federal law. To adopt the Officials’ contention would be to eliminate any obligation on the part of state officials to draw even the most obvious conclusions from well-settled federal case law until the precise state law at issue is struck down.” *Id.* at 1160 (citations omitted). Of course, as to same-sex marriage there is no “well-settled federal case law.” Whether the Court will advise California’s administrative agencies how (and when) to steer around section 3.5 if federal courts have spoken remains to be seen.

Observers of the oral arguments thought the Justices most unlikely to allow San Francisco officials to continue to implement their own constitutional vision. The decision is expected by the end of August.

Indiana Legislature Passes Endangered Industry Act: Take Note Spotted Owls!

By Cynthia Baker³

In Indiana, steel mills and aluminum foundries join the ranks of the endangered under Indiana’s Endangered Industry Act. Essentially, the Act protects “endangered industries” from various forms of regulation. An industry is “endangered” if it has experienced at least a 10% job loss or a 10% decline in production during previous calendar years.

The Act prohibits the adoption of any new rule by any Indiana rulemaking board or any new policy by the department of environmental management that would heighten regulation of endangered industries beyond that already in place under federal standards. The current statute extends the duration of the previous Endangered Industry Act for an additional year (until July 1, 2006). The 2004 version includes a new exception. The prohibition does not apply to an adoption of a new rule by Indiana’s Air Pollution Control Board that is necessary to attain or maintain the primary or secondary national ambient air quality standards. Because the act is in effect for less than five years, the act is not codified in the Indiana Code.

The full text of the bill is available at <http://www.in.gov/legislative/bills/2004/ES/ES0189.1.html>.

Can the State Appeal an Adverse ALJ Decision? Louisiana Court Topples the Temple

By Edward P. Richards⁴ and Kelly Haggar⁵

A district court in Louisiana has struck down virtually the entire edifice of administrative law judging in the state by declaring

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unconstitutional two state laws establishing a central panel of administrative law judges (ALJs).

The case of *J. Robert Wooley, etc. v. State Farm Fire & Casualty Insurance Co.*, et al. (No. 502-311, Division D 19th Judicial District Court, East Baton Rouge Parish, Louisiana, 2003), began as an apparently simple dispute between the Commissioner of Insurance and State Farm. Commission staff rejected a State Farm policy form for rental condos in February of 1996. After several years of unsuccessful meetings and correspondence, a "central panel" ALJ from the recently created Division of Administrative Law held, as a matter of law, that the form met the requirements of Louisiana insurance law and had thus been disapproved in error. The ALJ ordered the Commissioner to approve the challenged form in June of 1998. Within a month, the Commissioner filed for judicial review of the ALJ's ruling.

Because Louisiana had precluded most state agencies from appealing adverse rulings by ALJs when the central panel was established in 1995, State Farm argued that the Commissioner lacked standing. The trial court agreed in January 2000 and dismissed the Commissioner's petition for judicial review. The First Circuit upheld the trial court in *Brown v. State Farm*, 804 So. 2d 41 (2001), and the Supreme Court denied review. However, the panel did say that the Commissioner could seek a declaratory judgment challenging the statutory scheme or seek to enjoin enforcement of the ALJ's order approving the insurance form.

A different judge issued a preliminary opinion in May 2003 signaling that the Division of Administrative Law might be unconstitutional. The legislature responded to that threat by drafting a Constitutional amendment which granted the legislature explicit power to create a Division of Administrative Law and allowed an agency to appeal an adverse ALJ ruling. However, that amendment was resoundingly defeated in October 2003 (60% opposed).

Meanwhile, a full trial on the merits was held, which drew a crowd. Numerous *amici* filed briefs, among them the full Louisiana House (supporting State Farm while claiming to be neutral), the African-American Caucus (opposing State Farm), and several law professors (who argued that the law was unconstitutional). The trial court struck down the law in November 2003 in *Wooley v. State Farm*.

The law allowed a private person or corporation to appeal an adverse ALJ ruling but not the agency. This meant that questions of law could be decided by ALJs (who might not even be attorneys; only 9 of the 13 ALJs were lawyers) yet be immune from judicial review. Had this law been upheld, a state agency could have found a serious violation affecting health and safety, brought an administrative action to halt or correct the problem, been taken by the violator to an ALJ hearing, had the matter heard by a retired deputy sheriff with zero expertise in the matter, suffered an adverse ruling, and been totally without means of legal redress.

The court's opinion is available at http://biotech.law.lsu.edu/la/briefs/state_farm.htm.

Pennsylvania Supreme Court Strikes Down Statute That Forced Judiciary to Perform Executive Chores: Bright Line Separation of Functions

*By John Gedid*⁶

A Pennsylvania statute (Act) requires the state Department of Transportation (Department) to issue an ignition interlock restricted license to a driver convicted of a second or subsequent driving-under-the-influence (DUI) offense. When the court hearing the second or later DUI charge finds a driver guilty, the court must order installation of an ignition interlock device and certify to the Department that such device has been installed. The Pennsylvania Supreme Court held that the certification provisions of the Act violated separation of powers principles by imposing executive-branch duties on the judiciary. *Commonwealth v. Mockaitis*, 834 A.2d 488 (2003).

First, the Supreme Court held that general separation principles provide that no branch may exercise powers exclusively committed to another, and thus the judiciary has "historically" been protected from being forced into any areas other than adversary litigation. The court's function is limited to the determination of guilt, and a license suspension is a "collateral civil consequence" that does not belong with the judiciary. Separation of functions protects judicial impartiality; the certification requirement might compromise the ability of the judiciary to preside impartially if disputes about certification occur. Indeed, the court opined that *any* encroachment on the judicial power violates separation of powers.

Second, the provision of the Pennsylvania Constitution that establishes a unified judicial system commands strict separation. According to the Court, this provision clearly vests exclusive supervisory power in the Supreme Court over the entire judicial branch, which includes its employees. The Act's provisions "deputize" judicial employees to perform executive duties of inspection and certification that violate the Court's supervisory power. Moreover, the use of judicial resources for executive functions constitutes the imposition of an unfunded mandate on the judiciary.

This case continues the trend of interpreting the 1968 amendments to the Pennsylvania Constitution as a significant source of exclusive power to the judiciary. It appears to portend a strict, bright line approach to separation insofar as the judiciary is concerned and a rejection of any overlap between branches in separation cases. ○

⁶Professor of Law and Director of the Law & Government Institute at Widener University School of Law.

Essay *continued from page 3*

therapeutic devices added to the FDA's bailiwick; and the electric and natural gas industries brought under the FPC's purview. The Supreme Court's fresh reading of the Commerce Clause in *National Labor Relations Board v. Jones & Laughlin Steel Corp.*, 301 U.S. 1 (1937), sealed the "Deal," and the Fourth Branch became firmly affixed as a permanent arm of federal government.

The 40s, 50s and 60s sustained the regulatory momentum. 1947 ushered in the Atomic Energy Commission. The 1950s witnessed a boost in mining regulation with the Mine Safety Act of 1952. The landmark Civil Rights Act of 1964 greatly augmented the powers of the Civil Rights Commission, originally created in 1957. The Department of Transportation appeared in 1966 to oversee transportation safety. The Federal Coal Mine Health and Safety Act of 1969 set limits on coal dust in mine shafts.

When we get to the early 1970s, we see overt regulation ramping up again on the heels of growing inflation and unemployment, with the Nixon Administration embracing wage and price controls, and Congress enacting the Occupational Safety and Health Act, the National Environmental Protection Act, the Equal Employment Opportunity Act, and the Consumer Product Safety Act. Federal regulation had become so pervasive, there was practically no sector of the economy untouched. High inflation and unemployment persisted.

Sensing that perhaps certain markets might behave better if government controls were relaxed, President Ford took the first steps toward deregulation with the Railroad Revitalization and Regulatory Reform Act of 1976. Jimmy Carter followed suit by signing into law the Airline Deregulation Act of 1978, the Staggers Rail Act of 1980, and the Motor Carrier Act of 1980. In addition, Ford issued Executive Order 11821 requiring agencies to prepare inflation impact statements before issuing major regulations and legislative proposals, and Carter created the Regulatory Analysis Review Group to review up to ten rule-makings per year and submit comments and economic analyses for the record.

It is against this background of ninety years of progressively more intrusive and comprehensive regulation and only four

years, albeit the most recent, of movement in the other direction that Ronald Reagan entered office. Deregulation under Ford and Carter was significant but primarily limited to the transportation industry, which was among the most heavily regulated and most affected by rising oil prices. It was clear from Reagan's campaign speeches and first days in office that he viewed those accomplishments as merely a good start.

Some of Reagan's more conspicuous acts included: Executive Order 12287 (decontrolling crude oil and refined petroleum products); Executive Order 12288 (terminating President Carter's wage and price program); the Bus Regulatory Reform Act of 1982 (deregulating the intercity bus industry), and the Cable Communications Act of 1984 (deregulating cable television).

But Reagan's lasting contribution to the modern administrative state is to be found in the systematic overhaul of regulatory procedure and policy making. One of his first accomplishments in office was the establishment of a Presidential Task Force on Regulatory Relief charged with reviewing pending regulations and studying past regulations for the purpose of revising them and recommending legislative change. Executive Order 12291 quickly followed, centralizing review of agency rulemaking in the Office of Management and Budget (OMB) and requiring agencies to perform cost-benefit analyses of major rules. Later, Executive Order 12498 required agencies to submit to OMB an annual statement of regulatory policies, goals, and objectives for the coming year and information concerning all significant regulatory actions underway or planned. All of these processes are still with us today. They are not likely to disappear any time soon. And while all of the people will not agree all of the time with the purposes to which these processes are bent from administration to administration, the underlying goals of informed decision making and executive control, most will agree are legitimate governmental concerns. And we can all agree that in the right hands these processes are capable of yielding beneficial results, even if we do not agree on whose hands those might be. That is the Reagan legacy. That is his due. May he rest in peace. ○

News from the Circuits *continued from page 25*

show that its over reporting is inaccurate. The court also discussed penalty determination principles at length. In particular, it rejected the government's attempt to use a high interest rate derived from general economic data, requiring instead that the penalty be closely tied to the actual costs of the particular company.

Finally, the Eighth Circuit held that a decision by a state administrative agency has a *res judicata* effect in a federal action only if Congress so intended. *Iowa Network Services, Inc. v. Qwest Communications*, 363 F.3d 683 (8th Cir. 2004) involved the relationship between local telephone companies ("local exchange carriers" or "LECs") and Qwest, a wireless company that was paying long distance charges for its customers' calls to customers of the LECs. In response to Qwest's argument, the Iowa Utilities Board held that wireless calls within Iowa should be considered local, so that Qwest should not have to pay long

distance access charges for those calls. The LECs then sued to enforce their tariffs in federal district court, which gave *res judicata* effect to the IUB decision. Acknowledging that a state administrative decision can sometimes have preclusive effect in federal court, the Eight Circuit held that, "In the interpretation of a federal statute, the question of whether a state administrative agency's decision should be given preclusive effect is 'not whether administrative estoppel is wise but whether it is intended by the legislature.'" *Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 108 (1991). In light of Congress' evident intent to assert federal control over the telecommunications industry, the court held that Congress did not intend state decisions to control implementation of the Telecommunications Act. Thus, despite identity of the parties, facts, and issues, the Iowa decision did not have preclusive effect. ○

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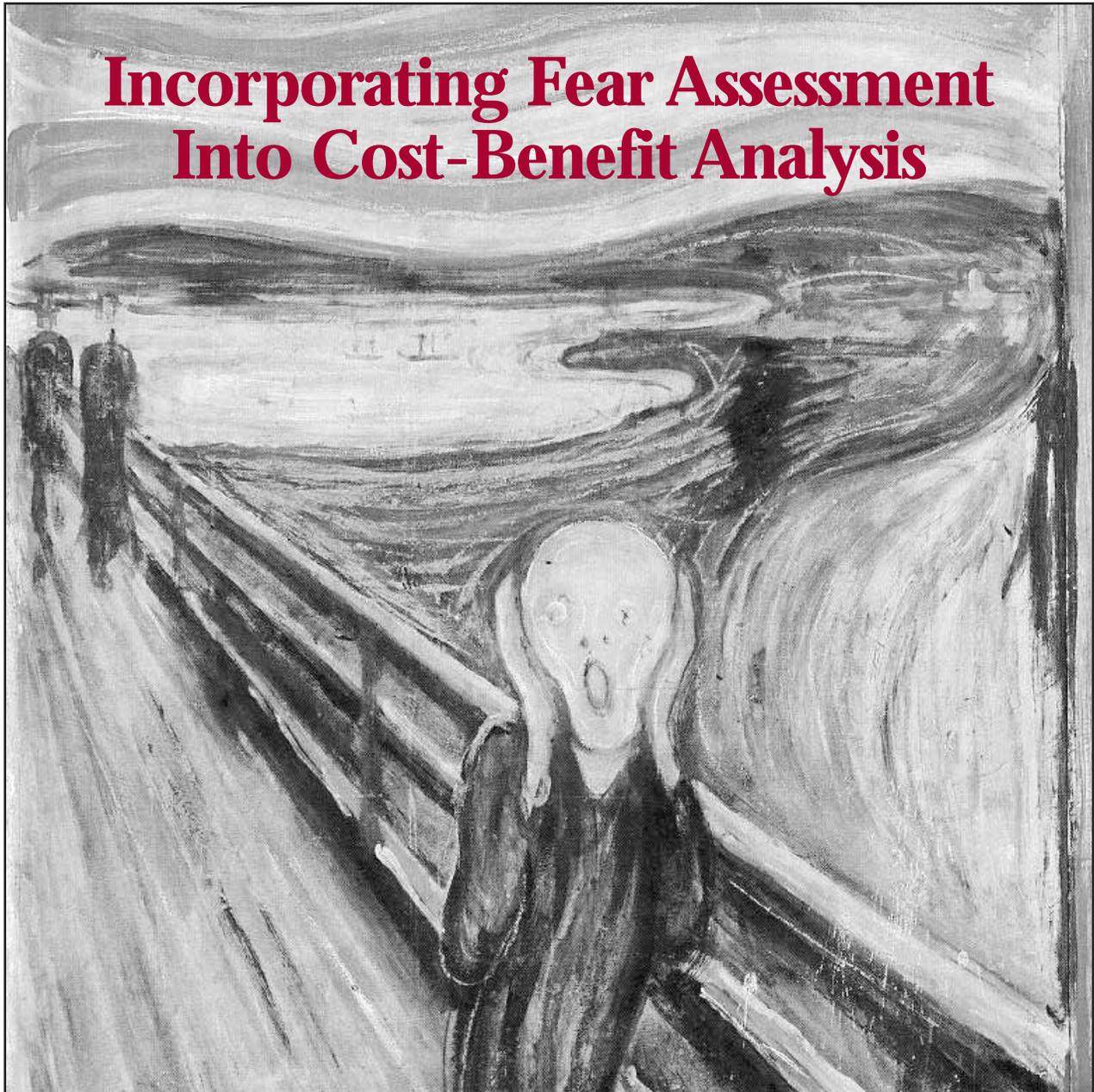
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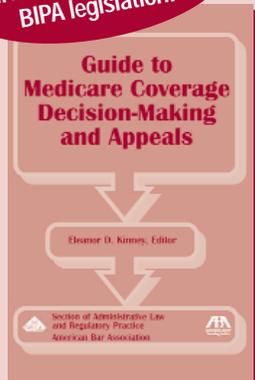
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