

ADMINISTRATIVE & REGULATORY LAW NEWS



Section of Administrative Law & Regulatory Practice

Vol. 32, No. 3

American Bar Association

Spring 2007



Healthcare Reform Roundup

New Governance
Federalization of Mandatory Benefits
Protecting Privacy

Also In This Issue

Executive Oversight of Agency Guidances

Judicial Review of Agency Manuals

2007 SPRING MEETING ■ MAY 18-20 ■ AUSTIN, TX

Chair's Message



Daniel E. Troy

I am pleased to report a number of exciting projects the Section is undertaking. In 2000, the Section compiled a list of recommendations for the President-elect and the new administration. The list was deliberately compiled before the winner of the election was known. The point was to come up with recommendations that commanded a broad consensus, and that would be “good government” whether adopted by a Democrat or a Republican. We are re-starting that process, to the end of having something ready before November 2008. Although that may seem a long time off, in “ABA-time,” that is just around the corner. Accordingly, at the recent Midyear Meeting, we discussed different subject areas, a process for developing these recommendations, and who should serve on an advisory committee. We are in the process of selecting those advisory committee members, and polling Section committees for different topics to address. We intend to have a series of robust discussions of these issues at the upcoming Spring and Fall meetings. We expect to produce an initial draft of the report by next year’s Midyear Meeting in Los Angeles. We hope to debate a final draft of the report at the Spring Meeting in 2008, and receive the Section Council’s approval of the recommendations at the 2008 Annual Meeting in New York. The final report will be ready in October of 2008.

The point of this exercise is not just to bundle up existing Section policy recommendations and transmit them to the new Administration. Rather, it is to sift through those recommendations and assign them some priorities. During this process we also hope to identify any ideas that we believe should be considered as new recommendations for Section policy for inclusion in the Report.

When I became FDA Chief Counsel, I was very eager for a “blueprint” of reforms to champion. The process of learning a senior position in the federal government, and trying to handle the day-to-day press of business, makes it very difficult for new members of an administration to spend much intellectual capital coming up with ideas for reform. I would have welcomed a list of suggestions, developed on a bi-partisan basis, commanding widespread and expert support. That is what we hope to accomplish in the realm of administrative law. If you are interested in joining this effort, please don’t hesitate to let someone in the Section leadership know of your willingness to assist.

In addition to kicking off this project in balmy Miami (while the rest of the country shivered under a horrible cold snap), we also held another of our periodic long range planning meetings. Among the topics we discussed were a desire to beef up our activities in the pro bono realm. Much of the pro bono work that many lawyers and firms do is, in fact, administrative law. Immigration, benefits, family law matters all have very significant administrative law components. There is much that the Section can do to foster these worthy efforts. Other long-

term goals we discussed were the reauthorization of the Administrative Conference of the United States—the Section’s top legislative priority—a project trying to improve rulemaking, and a wrap-up of the EU project. (A more comprehensive summary of the long-range planning meeting may be found in Section News & Events elsewhere in this issue).

We addressed two other major substantive issues in Miami. There was a vigorous debate about the changes to Executive Order 12866, which empowers OMB’s Office of Information and Regulatory Affairs (OIRA) to review regulations before they are issued. On January 18, 2007, the President extended OIRA’s authority to significant agency guidance documents. The revised order, and the accompanying OMB bulletin, encouraged informal notice and comment procedures for important guidance instruments. These changes, which are in line with existing ABA policy that emanated from our Section, did not cause much controversy. More attention, and concern, was directed to questions about the executive order’s encouragement of formal rulemaking, the lack of clarity about whether it extends to independent agencies, and whether the Regulatory Policy Officer, who appears to be newly empowered under the EO, must be an official who has been subject to the advice and consent of the Senate. The debate was in the best traditions of the Section, with experts in the area genuinely struggling with the meaning of the changes, and with the question of how to raise the Section’s concerns with the Administration in a constructive manner.

The other substantive discussion concerned agency preemption, which we addressed in a panel about which I can say little, given that I was a participant. Past Section Chair Bill Funk, who will co-chair a multi-Section task force on the question, moderated the discussion. Professor Sid Shapiro of Wake Forest University Law School contended that agencies’ assertion of preemptive effect does not warrant Chevron deference, and Charlotte Bahin of Lord, Bissell and Brook in Washington, DC updated us on preemption developments in the banking arena, which include a case pending before the U.S. Supreme Court. Our traditional Saturday night dinner turned out to be substantive and illuminating, as well as delightful, given the outstanding talk we heard from former HHS Secretary and current President of the University of Miami Donna Shalala. Her insights into the interactions with the Presidential Personnel Office, as well as her war stories about the Clinton Administration, proved both humorous and insightful.

That is the image with which I want to close—one which, I hope, captures our Section’s activities. Even if not always quite hilarious, they are always fun, but also intellectually satisfying. We have another outstanding program planned for Austin in May, a university and capital city also known for its lively music and entertainment scene. We hope to see you there! 

Table of Contents

Chair's Message	Inside front cover
The Case for Federalizing Mandated Health Benefits	2
New Governance and Soft Law in Health Care Reform	4
Health Insecurity: The Vulnerability Of Electronic Personal Health Information	7
Executive Order, OMB Bulletin Focus on Guidances	10
Judicial Review of Agency Noncompliance with Public Land Manuals	13
2007 Spring Meeting	16
Supreme Court News	18
News from the Circuits	20
Recent Articles of Interest	23
Section News & Events	25
News from the States	27
The Third Annual Administrative Law and Regulatory Practice Institute	28

ADMINISTRATIVE & REGULATORY LAW NEWS

Editor in Chief: William S. Morrow, Jr., Executive Director/General Counsel, Washington Metropolitan Area Transit Commission

Advisory Board Chair: Michael Asimow, Professor of Law Emeritus, UCLA Law School

Advisory Board Members: Robert A. Anthony, University Foundation Professor Emeritus, George Mason University School of Law; Warren Belmar, Partner, Capitol Counsel Group, L.L.C.; Daniel Cohen, Chief Counsel for Regulation, U.S. Dept. of Commerce; John Cooney, Partner, Venable, LLP; Cynthia A. Drew, Associate Professor of Law, University of Miami School of Law; William Funk, Professor of Law, Lewis & Clark Law School; Philip J. Harter, Earl F. Nelson Professor of Law, University of Missouri—Columbia School of Law; James T. O'Reilly, Visiting Professor of Law, University of Cincinnati College of Law

Contributing Editors: Yvette M. Barksdale, Associate Professor of Law, The John Marshall Law School; Robin Kundis Craig, Associate Professor of Law, Indiana University School of Law, Indianapolis; William S. Jordan III, C. Blake McDowell Professor of Law, The University of Akron School of Law; Edward J. Schoenbaum, Administrative Law Judge, Illinois Department of Employment Security

The Administrative & Regulatory Law News (ISSN 1544–1547) is published quarterly by the Section of Administrative Law & Regulatory Practice of the American Bar Association to provide information on developments pertaining to administrative and regulatory law and policy, Section news, and other information of professional interest to Section members and other readers.

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.

Manuscripts should be e-mailed to: knighk@staff.abanet.org. Articles should generally be between 1500 and 2500 words and relate to current issues of importance in the field of administrative or regulatory law and/or policy. Correspondence and change of address should be sent to: ABA Section of Administrative Law & Regulatory Practice, 740 15th Street, NW, Washington, DC 20005–1002.

Nonmembers of the Section may subscribe to this publication for \$28.00 per year or may obtain back issues for \$7.00 per copy. To order, contact the ABA Service Center, 321 North Clark Street, Chicago, IL 60610, Tel. 800/285-2221.

©American Bar Association 2007. Articles appearing in this publication may not be reprinted without the express permission of the ABA.

The Case for Federalizing Mandated Health Benefits

By Amy B. Monahan*

Every state currently regulates the substantive provisions of health insurance contracts by requiring coverage for certain procedures, treatments, or providers. Such substantive requirements are referred to as “mandated benefit laws.” States average eighteen health insurance mandates, with a low of two mandates in Idaho and a high of thirty-five mandates in California. These state mandated benefit laws are the subject of frequent criticism, both because of their perceived effect on health insurance coverage rates, and because of the inequitable manner in which they apply to the various providers of health coverage. This article will briefly explain the policy rationale behind mandated benefit laws, and explore possible reform options, arguing that federalizing mandated health benefits represents the best avenue for reform.

Mandated Health Benefits Rationale

States typically enact mandated health benefit laws in order to spread the risk of certain medical expenses across the entire state insured population in an effort to avoid adverse selection and its related problems. With a state law requiring coverage for disease X in every health insurance contract, the health insurance applicant who knows or has reason to suspect that he or she will need treatment for disease X does not need to request a special rider to cover the treatment. And insurance companies, instead

of pricing individual riders for the treatment, spread the cost of treating disease X among the entire insured population of the state. The result is that those without disease X pay slightly more for their health insurance, but those with disease X do not find themselves priced out of effective health insurance. State benefit mandates effectively force low-risk individuals into the risk pool, allowing insurers to price the insurance at an average market rate (taking into account the population-wide risk) rather than based on the individual’s expected risk.¹

State mandates can also help to address the cognitive biases of health insurance purchasers, as well as externalities. One form of cognitive bias is optimism bias on the part of the purchaser. Optimism bias occurs when a purchaser consistently underestimates risks with which the purchaser is unfamiliar or deems controllable by personal action. Another form of cognitive bias, referred to as the availability heuristic, occurs when a purchaser uses memorability as a proxy for prevalence.² Mandated benefit laws can be designed to take into account, and address, suboptimal levels of insurance for certain conditions that may be caused by either cognitive biases or externalities.

The primary argument against state mandated health benefits is that such mandates increase insurance costs for the entire insured population, and therefore

lead to a lower overall level of health insurance coverage. While benefit mandates are thought to increase coverage levels for individuals affected by, or at risk for, the medical conditions that are the subject of benefit mandates, the resulting increased cost borne by low-risk individuals may increase their rate of uninsurance. Mandated benefits have also been criticized on the grounds that they increase moral hazard and represent rent extraction by interest groups, rather than sound health policy.

Mandated benefit laws are also criticized because of their inequitable application, caused by the preemption of such state laws by the federal Employee Retirement Income Security Act of 1974 (ERISA). ERISA broadly preempts any state law that “relates to” an employee benefit plan. But state laws regulating insurance, including mandated health benefit laws, are explicitly saved from ERISA preemption. However, self-insured employee benefit plans may not, according to ERISA’s preemption provisions, be regulated as insurance companies. The functional result is that employers that purchase insurance contracts to fund employee health benefits must comply with state mandated benefit laws, while employers who self-insure their employee health benefits are exempt from state mandates and subject only to ERISA’s very limited substantive health insurance requirements. In practice, this results in large employers (who are most likely to self-insure) enjoying the lowest regulatory burden, while small employers (who are least likely to self-insure) must comply both with ERISA’s requirements and any state mandated benefit laws. This disparity in regulation is hard to justify, particularly given that it provides those who are most likely to provide health coverage with the lowest regulatory burden, while

¹ Peter Siegelman, *Adverse Selection in Insurance Markets: An Exaggerated Threat*, 113 YALE L.J. 1223, 1230-31 (2004).

² See, e.g., Judith H. Hibbard et al., *Decision Making in Consumer-Directed Health Plans*, at 5 (2003), available at http://assets.aarp.org/rgcenter/health/2003_05_cdp.pdf; Paul Slovic et al., *Facts versus fears: Understanding perceived risk*, in JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES 466-67 (Daniel Kahneman et al., eds., 1982).

* Associate Professor of Law, University of Missouri – Columbia. This article draws on *Federalism, Federal Regulation, or Free Market? An Examination of Mandated Health Benefit Reform*, 2007 U. ILL. L. REV. (forthcoming), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=960554.

imposing a more significant regulatory burden on those who are already least likely to provide health coverage to employees.

Reform Options

There are three primary reform options available to address the current disparity in the regulation of health insurance: (1) exclusive state regulation of mandated benefits; (2) total federal preemption of state law, combined with complete deregulation of mandated benefits; and (3) total federal preemption of state law, combined with new federal-level regulation of mandated benefits.

The first reform option would be to repeal ERISA preemption as it applies to self-insured health plans, in order to give states the exclusive ability to mandate health benefits. From a normative perspective, this reform option is attractive. It would address the current regulatory inequities by making all employer provided health coverage subject to mandated benefit laws. However, it would also undermine a primary purpose of ERISA, which is to allow employers to offer a nationally-uniform package of benefits. The inefficiencies of having fifty different sets of health insurance regulation appear to significantly outweigh the benefit of equitable regulation, making exclusive state regulation an unappealing reform option.

A second possibility for mandated benefit reform would be for the federal government to completely preempt all state mandated benefit laws, and not replace it with new federal-level regulation. In other words, the second reform possibility is for the federal government to deregulate the substance of health insurance contracts.³ While deregulation would address the inequality present in current regulation, it would do so by completely eliminating mandated benefits. The primary argument to be made in favor of deregulation is a libertarian one.

By requiring the inclusion of certain provisions in a health insurance contract, the government is requiring some individuals to sacrifice their good for the benefit of others. Individuals are required to make a monetary sacrifice so that an individual with Disease X is able to receive affordable health insurance coverage. We are remiss if we treat the sacrifice involved in mandated benefits as unsubstantial, as it is possible that an individual will be unable to afford health insurance due to benefit mandates.

While it is true that studies suggest that health insurance costs would need to decrease substantially in order for take-up rates to increase (i.e., decrease much more than the savings that would be achieved by eliminating mandated benefits), there will be a certain number of individuals at the margin for whom mandated benefits means the difference between being able to afford health insurance or going without coverage. This sacrifice is potentially enormous, given the financial ruin that can result in the absence of health insurance and the expense of purchasing it. Deregulation would end this involuntary sacrifice by allowing insurance purchasers the freedom to decide the scope of coverage they desire, free from governmental interference. It should also increase insurance coverage rates by lowering the cost of coverage.⁴

Deregulation, however, completely eliminates the ability to use mandated benefits as a policy tool. It prevents the government from mandating that the risk associated with certain conditions be spread among the entire insured population, and it reintroduces adverse selection problems. Completely eliminating the policy tool that mandated benefits provides seems to fundamentally undermine one of the primary purposes of health insurance – to pool health risks. Without the ability to mandate benefits, we risk making adequate insurance

unavailable for certain high risk individuals. As a result, deregulation is an unappealing avenue for reform.

The final reform option, and the one that I find to be most compelling, is to shift the regulation of the substance of health insurance contracts to the federal level. While far from perfect, federal regulation would accomplish more than our current regulatory system. Benefit mandates would have near universal reach, thereby eliminating almost entirely adverse selection problems for the benefits mandated. All health insurance purchasers would have to play by the same rules. With an equitable regulatory regime, small employers would no longer face larger regulatory burdens than large firms. And because exit from the federal system is limited, the federal government would not be hampered by the pressures of jurisdictional competition when crafting mandated benefits policy.

While federal regulation would not significantly expand risk spreading, it would increase it modestly compared to the status quo. And while it may be more difficult to garner political support for mandates at the federal level, this is not necessarily a bad outcome. Because mandates tend to increase premium costs and cause a certain level of inefficiency, we may want a system that discourages the “easy” passage of such mandates. Mandates are an important policy tool that can be vital to ensuring adequate health coverage for individuals, but only if they are the result of informed policy deliberations. Rent seeking is certainly a concern under a system of federal regulation, but no more so than under our existing system. There will be greater incentive to rent seek at the federal level because the stakes are higher for the interest groups. However, it should also be harder for those groups to secure rents, given the increased public scrutiny of the federal legislative process and competition from rent-seekers with other objectives. Federal regulation would ignore the historic role of the states as innovators in health policy, but given the impotent role

³ I am not suggesting that the business of insurance be entirely deregulated, just that the federal government take away the power of the states to mandate substantive provisions of health insurance contracts.

⁴ Any increase in coverage rates is not, however, likely to be substantial. See Amy B. Monahan, *Federalism, Federal Regulation, or Free Market? An Examination of Mandated Health Benefit Reform*, 2007 U. ILL. L. REV. (forthcoming), manuscript at 24–25.

continued on page 19

New Governance and Soft Law in Health Care Reform

By Louise G. Trubek*

Health care reform is underway. To resolve longstanding health care problems, reformers are using new technologies, revising the role of public agencies, expanding the use of information, and creating flexible and participatory tools. These processes are based on an emerging set of practices that can be called “new governance,” “post-regulatory,” or “new proceduralism.”

These techniques are intertwined with the reenvisioning of how to improve health care. Reformers are using these new processes to tackle three health care conundrums: universal access, reducing racial and ethnic disparities, and embedding information technology. These new processes consist of six innovative mechanisms that are utilized to resolve the health care conundrums: 1) alternative sites; 2) consumer and patient participation; 3) different roles for government; 4) redesigned organizational forms; 5) alternative methods for dispute resolution; and 6) new regulatory tools. The new governance mechanisms are interacting with the older governance systems. The coexistence of the two systems creates different types of interactions. One interaction is a dynamic rivalry between the old and new, a second is orchestrating a multipronged strategy that incorporates new governance techniques with more traditional incentives, and a third is integrating traditional legal values into the new processes.

I. Health Care Reform: Three Stories

Stakeholders realize that the problems with the health care system can and must be tackled, even in this complex environment. Stakeholder groups include

* Clinical Professor of Law & Director of the Health Law Project, University of Wisconsin Law School. This article has been condensed from a longer version appearing in 3 Indiana Health Law Review 139 (2006).

physicians, health care providers, business, government, consumers/patients, and technology experts and entrepreneurs. A set of reformers is emerging from the stakeholders. These reformers are leaders in creating new techniques and theories that challenge the older systems. There are three specific conundrums where the reform efforts are directed: 1) achieving universal coverage; 2) embedding technology into health care delivery; and 3) attaining high quality care for all.

A. Universal Coverage

The lack of universal coverage has long been the most noted deficiency in U.S. health care. One solution is the incremental approach, which reassures business and providers who fear a government controlled, one-size-fits-all model for health care. It de-emphasizes the bureaucratic, single set of universal benefits and administration.

The incremental approach to universal coverage is proceeding on four tracks: 1) experimenting at the state level; 2) integrating networks with federal funding; 3) linking public and private coverage; and 4) incorporating coverage for the uninsured through pooling and incentives.

B. Embedding Technology

Reformers are pursuing major initiatives to embed technology in the health care system. However, there is reluctance in the medical community to invest in technology because of high costs, a perceived loss of autonomy in exercising professional expertise, and fear of a centralized data set. There is also difficulty in developing a national system that protects privacy and security.

C. Guaranteeing Quality and Equity

The reformers realize that just having health insurance is not enough to guar-

antee health; the care must be of high quality. Since the late 1990s, reformers from the medical sector and concerned business purchasers have promoted quality as an achievable and necessary goal for the health care system.

Studies have shown that minority Americans receive less health care, and what they do receive tends to be lower quality care, even when controlling for insurance status and income. In response to the documentation of the persistence of health disparities, there is a major initiative to adopt a quality-based approach to the provision of health care as an indirect route to achieving equality.

II. New Governance and Soft Law

Historically, in health care, there has been a mix of self-regulation, market forces, and government regulation. The health reform stories discussed earlier describe an emerging set of practices that can be called “new governance,” “post-regulatory,” or “new proceduralism.” New governance includes devolution of government, public-private partnerships, new types of regulations and incentives, network creation, coordinated data collection and dissemination, benchmarking, monitoring, and active individual involvement. Devolution moves power to lower levels of government, including local and state, and de-emphasizes inflexible nationally administered programs.

Experimentation is closely linked to devolution, since the more local an entity is, the easier is experimentation. Often, experimentation occurs outside of, or parallel to, regulation.

Another element is public-private partnerships. Here, traditionally isolated organizations and programs are brought together to work on shared problems, crossing barriers of diverse corporate forms and competing constituencies. The collection of data is emphasized in order

to evaluate whether goals that are set and benchmarked are achieved.

New governance is transformative of law in that it challenges what we think of as law. Guidelines, benchmarks and standards that have no formal sanctions are important elements in new governance. This can be called “soft law.” Soft law is an important component of new governance practices. “Hard law” can be characterized as command and control, court based dispute resolution, uniform rules, punitive sanctions, and court challenges for noncompliance. This approach has proved inadequate in many cases.

Soft law allows for learning and feedback. Further, soft law incorporates economic incentives into the governance framework while allowing for diversity and experimentation. It allows public and private domains, and different regulatory clients, to interact more easily.

III. Innovations

Increased information from evidence-based medicine and electronic records has created an explosion of new knowledge which depends on feedback and iteration. The use of benchmarking will lead to increased learning. The combination of linking information technology with evidence-based medicine, new roles for the actors, and aligning incentives can lead to redesign and innovation of health care practices.

These innovations that are being created are the key elements of new governance in health care. The first innovation is alternative sites that create locations for stakeholder interaction and implementation of programs and projects. The second innovation is the enhanced role of consumer/patient participation. The government’s role becomes a set of practices that can be employed differently depending on the specific problem to be resolved. The role of private organizations shifts as well. Alternative dispute resolution systems, rather than traditional court-based resolution, provide for redress for the individual. Finally, the new governance system uses information as a regulatory technique by publishing data on outcomes, offering fiscal incentives for good performance by hospitals and clinics, and issuing rules that allow

diverse ways of achieving positive outcomes.

A. Alternative Sites for Deliberation and Implementation

Reformers are creating new sites that encourage collaboration. The most common sites of collaboration consist of stakeholders that convene to solve health care problems or crises. These collaboratives exist at the local and state levels; there are national groups, as well. Participating at these sites are the health care stakeholders: providers, consumers, government, and employers.

Four sets of reformers are now emerging as proponents and leaders of alternative approaches to solve the health care conundrums through these new collaborations: pioneering physicians, concerned payers, active consumers, and facilitating government leaders. Each participant has a constituency that must accept working with the new alliances. These leaders must also change the culture of their constituency so the entire group accepts the value of collaboration and views it as a way to achieve its own goals.

B. Consumer and Patient Participation

One distinctive feature of new governance practices is the increasing and changing role of the patient and consumer. The patient and consumer are independent actors who can influence outcomes at the clinical and policy level. The use of public information based on data that enable the consumer to make choices will both improve the quality of care and the entire system.

The rise of consumers as key players in health care is related to the use of markets in health care to controlling costs and the increase in patient involvement to control chronic disease. Therefore, two consumer roles are important in health care: the role of the purchaser of healthcare services and that of the patient active in his own health care.

C. Disaggregated but Necessary: The Role of Government

Traditionally, the government’s primary role has been fiscal through the public budgetary process. Through its

fiscal capacity, the State can align various private players with public policy goals. The various ways in which government can be involved include facilitating collaboration, monitoring programs for effectiveness, collecting data, using regulation and funding to assure quality, correcting imbalances in participation, and sanctioning to ensure that actors participate in good faith.

D. New Corporate Forms

There is also a change in the governance of hospitals. The existing governance structures cannot cope with pressures such as pay for performance regulations, benchmarking for quality care, and embedding technology. As hospitals and clinics become larger integrated systems, there is also a move towards standardization of benchmarks and improved internal communication. This requires lawyers and compliance people to agree on systems in order for the information to be produced over the entire range of institutions and people responsible for institutions.

E. Alternative Dispute Resolution

The disillusion with traditional litigation has been ongoing for several decades. Two additional types of dispute resolution are emerging as part of changing governance. The first is independent external review, a dispute resolution system for health care contract claims. This system developed out of dissatisfaction with the managed care system and is a way of reasserting physician peer review and curbing excesses in cost containment. A second type of dispute resolution system is a version of restorative justice in nursing homes where there is a complaint against a staff member. Family members, residents, and if possible community and advocacy groups, meet with the nursing home staff and come up with a plan for improvement as a first step.

F. New Regulatory Tools

Another set of tools might be described as hitting the physicians and hospitals in their wallets and their egos. These three regulatory tools can be called: public information, financial

continued on next page

incentives tied to efficiency, and regulations that allow the institutions to develop diverse ways of successfully meeting the standards.

There is widespread development of data about outcomes and commitment to protocols. Participation by physicians and other health care professionals is required in the development of standards and benchmarks for credibility. Instead of rigid requirements issued after great debate, but often not revisited for many years, these systems are designed to be constantly updated and reviewed.

This information can affect performance through shaming and motivates the institutions to develop systems that obtain results. By gathering data and updating results on a regular basis, there is a constant reinforcement to improve performance. Another approach to improving performance is to align the incentives by tying financial payments to quality. A third approach may be referred to as management-based regulation. Management-based regulation is a mechanism that “directs regulated entities to engage in planning processes that are self-determined to meet a particular public goal.”

IV. Coexistence: Old and New, Multi-Pronged Strategies, and Legal Values

There are three examples of coexistence between old governance/hard law and new governance/soft law in health care stories. The first is dealing with medical error, where old and new models coexist as alternatives and potentially as rivals. The second is where a government agency takes on the whole range of new governance techniques and employs them as part of its regulatory and funding functions. The third route is the integration of traditional legal values as part of the new governance approaches: monitoring to ensure participation, assuring commitment to eliminating discrimination through maintenance of equal protection, and linking the right to health care to the achievement of a robust economy.

A. Dynamic Between Old and New

Coexistence between new governance and soft law and the traditional hard law

can occur through a dynamic rivalry. One example of the interrelationship between the two is the effort to move from the traditional medical malpractice and administrative sanctioning of physicians to a systemic increase in quality. The old governance system relied on medical malpractice and administrative physician sanctioning to guarantee quality and compensate injured parties. There is widespread agreement that the malpractice litigation system fails to compensate injured parties and to deter future negligence. Proponents of the quality assurance system assert that it will do a better job of deterring negligent behavior as well as preventing unnecessary errors.

B. Orchestrating Multi-pronged Strategies

In some cases there is coexistence between a traditional government agency and new governance techniques where they are yoked in a multi-pronged strategy that deals with complex problems. Orchestration is one example of a multi-pronged strategy. It uses new governance techniques to integrate new knowledge, encourage innovation, and allow for diversity. The government agency, however, relies on its traditional regulatory and funding roles to provide baseline incentives for participation in the new governance processes.

C. Integrating Legal Values

The New Deal/Great Society model for governance emphasized the need for universal “rights,” based on constitutional or statutory law. The function of rights can be seen as coexisting with new governance modes. This coexistence can be seen in the way traditional legal values must be maintained in order for new governance to be effective and legitimate. Three approaches to health care reflect the coexistence of these new governance techniques with legal values: inclusion in universal access, equity in health care treatment, and participation and transparency in health care decision making.

1. Inclusion

The long-standing battle for a “right to health care” underlies many of the

campaigns for universal provision of health care coverage. What is needed is a conceptualization of the relationship between hard law entitlements with soft law techniques such as experimental expansions of coverage and linking private employer based programs with public coverage. The merger of public and private programs is a way of achieving universal coverage where the poor will not be targets of inadequate funding and poor quality.

2. Equity

There are major initiatives underway to reduce disparities in race and ethnicity, but the role of rights is decentered in the new approaches. There is reliance instead on quality tools such as benchmarking, nationally accepted protocols for best practice, and patient self-management to eliminate disparities. However, the law of civil rights can be combined with the law of quality compliance. The civil rights community has maintained an interest in health care and the potential for legal remedies remains. Its role can include ensuring that public data dissemination is available and usable by outside groups.

3. Participation and Transparency

The values of participation and transparency are essential for a democratic system of governance. One approach to ensure participation is providing a system for explicit measurement of the participation of disadvantaged groups in these new sites. This requires guidelines for participation and monitoring to ensure that the guidelines are being met. In order to be legitimate, the processes must be visible and accountable.

Conclusion

This is an interesting time to look at alternative governance in health care. It is an opportunity to explore the implications of these alternatives and evaluate which types of regulation and governance work most effectively to achieve health care goals. Many innovations challenge conventional institutions, roles, and professions. They also challenge the way people participate in society and our view of how government and law can operate. ○

Health Insecurity: The Vulnerability Of Electronic Personal Health Information

By Sharona Hoffman* & Andy Podgurski**

Both patients and health care providers have much to gain from the electronic processing of health data. Its advantages include speed, efficiency, and flexibility of information processing, which can result in long-term cost savings and improved patient outcomes. In 2004, President George W. Bush announced a plan to ensure that all Americans' health records are computerized within ten years, and the U.S. Department of Health and Human Services (HHS) began developing a Nationwide Health Information Network.

Unfortunately, many of the positive attributes of medical record computerization enable the operation of a market in illicitly-obtained private health information. The Internet provides a nearly ideal channel for trafficking in health information because it allows data to be transmitted anywhere in the world quickly, inexpensively, and with relatively little risk of detection.

Various parties might be interested in personal health information for a variety of reasons. Employers wish to hire and retain the healthiest employees in order to avoid problems of absenteeism, reduced productivity, and high health

insurance costs. Lenders and other businesses seek clients who will be healthy enough to work and pay their bills. Drug companies hope to influence doctors' prescribing decisions, and advertisers and marketers wish to tailor their materials for particular audiences and thus can benefit from knowing which patients have what conditions. Insurers making eligibility and premium rate decisions concerning individual health, disability, life and other insurance policies also have an interest in health status data. Even educational institutions might wish to recruit and accept students with the greatest potential for success and longevity. In a world in which electronic health information is vulnerable to theft and computer hacking, it could also become increasingly of interest to blackmailers and other criminals. For example, after a computer was stolen from a general medical practice, two prominent women received letters from blackmailers who threatened to disclose that the women had had abortions. Even single people who are looking for a low-risk romantic partner might try to obtain personal health information about other singles if it were easily available.

The confidentiality of personal health information in fact appears to be compromised with alarming frequency. Various reports reveal that organizations sell or donate old computers without removing confidential information contained on their hard drives, including the names of patients who have AIDS and mental illnesses. One case involved a banker who served on a state health commission and obtained a list of all cancer patients in his state, which he used to cancel the individuals' loans. On April 26, 2006 Aetna announced that a laptop computer containing personal information concerning 38,000 consumers had

been stolen. Hackers from Germany hacked into the computer system of Akron Children's Hospital and were able to access tens of thousands of records in October 2006. These are just a very few examples of phenomena that are unfortunately becoming increasingly familiar.

In order to address the threats to data security associated with the electronic storage and transmission of private health information, HHS enacted the Security Rule, which is part of the Privacy Rule under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The HIPAA Security Rule, which is enforced by HHS's Centers for Medicare & Medicaid Services (CMS), became effective on April 20, 2005, for most covered entities. Under the Rule, electronic protected health information (EPHI) includes "individually identifiable health information" that is electronically or otherwise transmitted or maintained. The Rule, as it is currently written, covers only health plans, health care clearinghouses, and health care providers who transmit health information electronically.

The HIPAA Security Rule

The Rule imposes four general requirements upon covered entities. They must 1) ensure the "confidentiality, integrity, and availability" of EPHI; 2) safeguard against reasonably anticipated security threats to the data; 3) protect against reasonably anticipated impermissible uses and disclosures of the data; and 4) ensure that the workforce complies with the Rule.

The HIPAA Security Rule's requirements appear in two forms: standards and implementation specifications. The implementation specifications, in turn,

continued on next page

* Associate Dean, Co-Director of Law-Medicine Center, Professor of Law, and Professor of Bioethics, Case Western Reserve University School of Law.

** Associate Professor of Electrical Engineering and Computer Science, Case Western Reserve University. B.S., M.S., Ph.D., University of Massachusetts. This article is based on a longer piece entitled "In Sickness, Health, and Cyberspace: Protecting the Security of Electronic Private Health Information," 48 BOSTON COLLEGE LAW REVIEW ___ (forthcoming Spring 2007). See also Sharona Hoffman & Andy Podgurski, *Securing the HIPAA Security Rule*, ___ J. INTERNET L. ___ (forthcoming 2007).

also are of two kinds: required and addressable. The required implementation specifications are mandatory, but the addressable implementation specifications can be handled in several ways. First, they can be implemented “if reasonable and appropriate.” Second, a covered entity can document why implementation is not “reasonable and appropriate” and implement an equivalent measure if a suitable one is available.

One section of the HIPAA Security Rule is devoted to administrative safeguards. The general standards articulated in this section focus on the following areas: security management processes, workforce security, information access management, security awareness and training, security incident procedures, and contingency plans. The implementation specifications mandate risk assessment, the establishment of a sanctions policy for non-compliant employees, workforce clearance procedures, log-in monitoring, password management, and many other measures.

The physical safeguards section of the Rule features four standards addressing facility access controls, workstation use, workstation security, and device and media controls. Pursuant to the implementation specifications, covered entities must develop a variety of plans and procedures including, for example, ones related to facility security, access control and validation, and data backup and storage.

The Rule’s technical safeguards section features five standards. These require the establishment of procedures to control access to EPHI, to audit activity in information systems that process EPHI, to protect EPHI from improper modification or elimination, to obtain authentication from those seeking access to EPHI, and to protect EPHI. The implementation specifications address matters such as encryption and decryption and mechanisms to authenticate EPHI.

There is also a provision that focuses on contracts with business associates. It details methods by which to ensure that business associates properly protect the integrity and confidentiality of EPHI. Although it is found in a different section

of the HIPAA Privacy Rule (not in the Security Rule), the “uses and disclosures” provisions must also be highlighted. These subsections prohibit the utilization and dissemination of EPHI without the patient’s consent except in specific, enumerated circumstances that generally relate to medical treatment or obligations established by law.

Critique of the Security Rule

We now turn to a critique of some of the Security Rule’s major shortcomings.

Scope of Coverage

First, the narrow definition of “covered entity” limits the Security Rule’s efficacy because the threat to EPHI extends well beyond health plans, health care clearinghouses, and health care providers.

We recommend that the definition of “covered entity” be expanded to include “any person who knowingly stores or transmits individually identifiable health information in electronic form for any business purpose related to the substance of such information.” This definition is designed to avoid the problems of being either under-inclusive or over-inclusive. Thus, while it will significantly extend the Security Rule’s reach, it will not capture benign circumstances such as private citizens e-mailing each other about a friend’s illness or church volunteers arranging food deliveries for the sick or assistance for the disabled.

Expanding the definition of “covered entity” would have wide-ranging effects. Most importantly, it would extend the regulations’ use and disclosure limitations to employers, financial institutions, marketers, data miners, and many others handling EPHI. Thus, those who wish to use EPHI or disclose it to other parties would need to obtain authorization from the data subjects.

This policy will adversely affect marketing and data mining operations, which are plentiful in the health care arena. Several databases already sell lists of persons suffering from a large number of ailments. These sources include the Medical Marketing Service and Hippo Direct Medical Maladies Direct Marketing Lists. In addition, health care information companies sell

individual physicians’ prescribing records to pharmaceutical companies that use them to market particular drugs to specific doctors. These lists are not necessarily compiled by illegal means. Rather, medical and other personal data can often be purchased or mined from sales information, supermarket savings cards, surveys, sweepstakes and contest entries, U.S. Census records, credit card transactions, phone records, credit records, product warranty cards, or public records that are rightfully in the possession of those aggregating the information.

If the Security Rule were to cover marketers, advertisers, and sellers of EPHI, these parties would be required to obtain authorization from data subjects to carry out their activities. This, however, would not be impossible to do. Many consumers may be happy to provide consent if the request to use the data is carefully crafted and they are told, for example, that their EPHI “will be used to identify products that will better fit your needs.”

Right of Inquiry

A second criticism relates to patients’ rights. The HIPAA Privacy Rule allows patients to inspect and obtain copies of their EPHI from covered entities as well as to request corrections to erroneous information, but it does not allow data subjects to establish the provenance of the data or inquire about the manner in which it is used. If the Security Rule is expanded to cover many different types of entities that possess EPHI, including marketers, employers, financial institutions, etc., it will become important for data subjects to have the right to establish the origins of the data and ask questions about how it has been used. Consequently, if a data subject becomes aware that an unexpected party possesses her information, she will have a way to conduct a preliminary investigation and determine whether it was distributed inappropriately without her authorization. This mechanism should serve as a deterrent to malfeasance and should incentivize covered entities to engage in due diligence to determine the legitimacy of EPHI suppliers.

The regulations allow covered entities to charge reasonable fees for processing requests for information, so organizations should not be over-burdened by frivolous inquiries. The response system could also often be automated with websites to which data subjects can submit queries and which can provide boilerplate responses, when appropriate.

Insufficient Guidance

Third, the Security Rule allows covered entities tremendous discretion with respect to its implementation. It provides that they may choose the means by which to “reasonably and appropriately” implement the Rule’s standards and implementation specifications, so long as they consider their size, complexity, capabilities, and technical infrastructure in making their decisions along with the costs of implementation and the risks of security breaches. This, however, is a misguided approach. Most covered entities will not have the expertise to conduct sophisticated risk analyses or be able to choose and employ appropriate computer security measures. Large entities that do have the resources to do so could use this vacuum of guidance as justification for implementing minimal security safeguards.

The project of crafting fixed rules for a dynamic technical domain constitutes a significant challenge because computer technology and its associated security risks are ever-changing. One mechanism to address this problem is a best practices standard. We recommend that the Security Rule require covered entities to “make reasonable efforts to identify and employ best practices relating to security measures, software development, validation, and maintenance, and software system administration that are either commonly used by similarly-situated business entities and governmental institutions, or can be clearly demonstrated to be superior to best common practices.” This approach provides guidance while still maintaining flexibility and sensitivity to the fast evolving computer technology environment.

How will covered entities determine what best practices are? Most will not have the ability to do so themselves. We antici-

pate that the majority will hire security product vendors in order to achieve regulatory compliance. These vendors should be certified either directly by the government or by certifying organizations that are themselves licensed by CMS.

Many tools and technologies that can facilitate Security Rule compliance already exist. The National Institute of Standards and Technology (NIST), for example, has published the NIST Risk Management Guide for Information Technology Systems, which provides useful guidance concerning risk assessment and management. The International Organization for Standardization (ISO) and the International Engineering Council have published a variety of standards describing sound information security practices. ISO 27799 entitled “Health informatics – security management in health using ISO/IEC 17799,” is particularly relevant and is due to be published in 2007 if it is approved. In addition, the Computer Emergency Response Team (CERT), a federally funded organization, offers security alerts and solutions through its website. A variety of turnkey solution products are advertised as specifically addressing HIPAA Security Rule requirements. A simple Google search revealed quite a number, including Advanced MD, HipaaManager HCAT, and others. It is likely that increasingly sophisticated and cost-effective tools will continue to be developed in response to marketplace demands for security technology.

Public interest organizations that are concerned about health information security could also distribute materials designed to educate the public about best practices relating to computer security. Furthermore, CMS could maintain a website on which covered entities could post input concerning security practices that they have utilized. The information should be open to the public, easily searchable, and organized by industry size and type so that covered entities could find data concerning similarly-situated organizations.

Private cause of action

The last problem upon which we will focus is the Privacy and Security Rules’

lack of a private cause of action. Enforcement of the Privacy Rule is assigned exclusively to HHS. However, the agency has been criticized for grossly deficient enforcement of the HIPAA Privacy Rule. Between April 14, 2003 and June of 2006, HHS received 19,420 complaints concerning violations of privacy. Yet, no civil fine has been imposed, and only three criminal actions have been brought to date under HIPAA’s criminal enforcement provision.

According to a summer 2006 survey conducted by the Healthcare Information and Management Systems Society and the Phoenix Health Systems, covered entities are failing to comply with the HIPAA Security Rule at an alarming rate, perhaps because of its anemic enforcement. The survey elicited responses from 178 providers (hospitals and physician practices of different sizes) and 42 payers (health insurers). Only 56% of providers and 80% of payers represented that they had achieved HIPAA Security Rule compliance. The reasons articulated for non-compliance included the organizations’ deciding to prioritize other projects, monetary constraints, and difficulty integrating new systems and procedures into existing infrastructure. Upon further inquiry, the researchers determined that even those who claimed to have complied fully had not in reality done so. In fact, 39% of providers and 33% of payers had suffered security violations during the six months prior to the survey. Consequently, a private cause of action is critical in order to establish meaningful deterrence and provide a remedy for individuals who are injured by security breaches.

Conclusion

The recommendations outlined in this article should both facilitate Security Rule compliance and further induce covered entities to adhere to regulatory requirements. They are designed to empower the Security Rule to furnish data subjects with much more meaningful and comprehensive data safety so that the growing use of EPHI does not generate a parallel growth of privacy and confidentiality breaches. ○

Executive Order, OMB Bulletin Focus on Guidances

by Robert A. Anthony*

A new Executive Order, E.O. 13422, gives presidential recognition to the importance of federal agency guidances and the problems they can raise. While the specific mandates of the January 18 Order and the accompanying OMB Bulletin are narrowly drawn, the focus they cast upon the need to confine and regularize agency guidances is of potentially enormous significance. The Bulletin, particularly, strongly affirms that agencies should not misuse guidances—which lack the procedural foundations to carry the force of law—by treating them as binding upon the public.

Guidances come in many forms, such as guidelines, policy statements, memorandums, manuals, interpretations, press releases, circulars, bulletins, speeches, Dear Manufacturer letters, Q and As, and the like. The Order amends the well-known Clinton Executive Order concerned with regulations (E.O. 12866), by bringing guidance documents within its coverage. Independent regulatory agencies like the FCC continue to be generally exempt from the Order.

The Order and Bulletin establish good practices for guidances, and subject “significant guidance documents” to review by OMB’s Office of Information and Regulatory Affairs (OIRA).

Executive Order 13422

Under the amended Executive Order, OIRA’s review of a “significant guidance document,” while substantial, is considerably less intensive than its review of a “significant regulatory action.”

A “regulatory action” is an action, such as a notice of inquiry or a notice of proposed rulemaking, that promulgates

or is expected to lead to a final regulation. It is “significant” if it is likely (a) to lead to a rule having an annual effect on the economy of \$100 million or more or to adversely affect the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state or local or tribal governments or communities, or (b) to have certain budget impacts or to raise inconsistencies or novel issues. A “guidance document” is an agency statement—which is of general applicability and future effect but is not expected to result in a regulation. It is “significant” if it may be anticipated to lead to the kinds of effects in (a) and (b) just mentioned. (Presumably, to be “significant,” a guidance raising a “novel” issue must have potentially substantial consequences.)

An agency proposing a “significant regulatory action” must provide OIRA with a text of its draft, with a description of the need for the regulation and how the regulation will meet that need, and with cost and benefit analyses. For significant regulatory actions meeting the criteria in (a) above, more detailed assessments of benefits and costs and of feasible alternatives are required. OIRA publicly discloses certain information, especially concerning its interchange with the agency and any *ex parte* communications. The agency may not publish its action until OIRA has reviewed it in light of the Order’s regulatory principles and has resolved any concerns; unresolved disagreements are to be resolved by the President.

The new provisions governing “significant guidance documents” call for the agency to give OIRA advance notice of the document. Then, if requested by OIRA, the agency must provide to OIRA “the content of the draft guidance document, together with a brief explanation of the need for the guidance

document and how it will meet that need.” OIRA “shall notify the agency when additional consultation will be required before the issuance of the significant guidance document.” The consequences in the event of disagreement are left unstated. A revised provision says that nothing in the Executive Order shall affect the authority vested by law in an agency or its head. So at least in theory the agency head could issue a significant guidance without OIRA’s concurrence, but in practice that seems unlikely to happen often. No express provision is made for disclosure of interchanged materials or other information regarding the guidance.

This new review structure, while not as rigorous as that for proposed regulations, will impose a regime of discipline upon the development and issuance of major guidances. Too often guidances have been concocted and issued without regard for the important general principles of sound regulatory practice that the Executive Order now directs full attention to.

The Order amends several of its regulatory principles to require that they be observed for guidance documents in the same way they are observed for regulations—for example, to use best information before issuance, to avoid inconsistencies, to minimize burdens, and to be consistent with the President’s priorities.

A separate amendment encourages agencies, in consultation with OIRA, to “consider whether to utilize formal rulemaking procedures under 5 U.S.C. 556 and 557 for the resolution of complex determinations” in the development of significant regulatory actions. Use of the Administrative Procedure Act’s 556–557 trial-type procedures for rulemaking has been widely discredited, primarily because it takes initiative away from the agency and engenders delay. Unless specific factual issues upon which regulations will be based cannot be

* Section Fellow; Vice-Chair, Judicial Review; Vice-Chair, Rulemaking; GMU Foundation Professor of Law Emeritus, George Mason University School of Law.

resolved by any other means, those procedures should be avoided.

OMB's Final Bulletin for Agency Good Guidance Practices

The accompanying OMB Bulletin's mandates upon the agencies are narrow: (1) to observe standards of good practice, including public access and feedback, in issuing and publicizing significant guidance documents, and (2) to observe a form of "notice and public comment" procedure for *economically* significant guidance documents, as described below.

But the Bulletin is most noteworthy for its emphasis on "the non-binding nature of guidance documents," a precept found in various formulations throughout the 18-page preamble.

Non-Binding Nature of Guidances

A blight on government practice has been agency use—misuse—of guidances to bind members of the public. Guidances cannot have the force of law because, in almost all cases, they are documents that have not been promulgated through the notice-and-comment procedures mandated by the APA for valid regulations. They nevertheless can be and often are put forth in such a way as to have practical binding effect on members of the public. If an applicant wants a permit or a benefit or an approval, he or she may have to conform to a guidance, even though it was not promulgated as a regulation through proper notice-and-comment procedures. Or an agency may threaten enforcement for nonconformity to a guidance, even where no statute or regulation was violated.

The Bulletin declares that one of the purposes of its Good Guidance Practices is "to ensure that guidance documents of Executive Branch departments and agencies are: . . . not improperly treated as binding requirements." It states that "Nothing in this Bulletin is intended to indicate that a guidance document can impose a binding requirement."

These precepts are reflected in the requirement that significant guidance documents "[n]ot include mandatory language such as 'shall,' 'must,' 'required,' or 'requirement,' unless the agency is

using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose agency consideration of positions advanced by affected private parties."

Although the mandatory provisions of the Bulletin deal only with "significant" guidance documents, the language and thrust of the preamble speak to guidances generically, and its declarations about the non-binding nature of guidances and the impropriety of treating them as binding apply to all guidances great and small.

The Bulletin notes the misuse of guidances: "Because it is procedurally easier to issue guidance documents, there also may be an incentive for regulators to issue guidance documents in lieu of regulations," quoting a famous passage from the *Appalachian Power* case, 208 F.3d 1015, 1019 (D.C. Cir. 2000). It adds: "The courts, Congress, and other authorities have emphasized that rules which do not merely interpret existing law or announce tentative policy positions but which establish new policy positions that the agency treats as binding must comply with the APA's notice-and-comment requirements, regardless of how they initially are labeled."

The insistence on the nonbinding effect of guidances is of signal importance. The Executive Office of the President has joined in condemning the misuse of guidance documents for binding the public.

It is not too much to say that an essential distinction between democracy and autocracy depends on whether government observes democratically-legislated authority and procedures when it places rights and obligations upon its citizens. Our federal system, with some exceptions, requires APA notice-and-comment for rules of general applicability if they are to have the force of law—that is, if they are to be binding on members of the public. Guidances that are not so promulgated cannot legitimately bind.

Neither the Executive Order nor the Bulletin in any way diminishes the APA's requirements.

While only the subset of "significant" guidances is regulated by the Executive Order and Bulletin, both instruments contain this useful general definition:

"The term 'guidance document' means an agency statement of general applicability and future effect, other than a regulatory action (as defined in Executive Order 12866, as further amended, § 3(g)), that sets forth a policy on a statutory, regulatory or technical issue or an interpretation of a statutory or regulatory issue." Much of the Bulletin's preamble states practices and legal circumstances applicable to all guidances, the great majority of which will not be "significant."

The Bulletin's definition of "significant guidance documents," which are subjected to procedures more extensive than those required by the APA, expressly excludes certain categories, which consequently need not endure the additional procedures. But exemption from those procedures does not create an exemption from APA requirements.

For example, speeches and press releases are not "significant," but in particular cases they may be vehicles through which new agency regulatory policy is promulgated. Although outside of the Bulletin definition, these formats do not supply avenues of escape from APA notice-and-comment requirements.

Also excluded from the Bulletin definition of "significant" are "purely internal agency policies" and "internal guidance documents directed solely to other Federal agencies." Most such documents operate on a general policy plane, and are subject to further implementation before their substances are applied to persons outside the agency. But if a purportedly "internal" document definitively affects the established rights and obligations of private persons—for example, by changing the criteria by which entitlements are granted or specific regulatory requirements are satisfied—it should get APA notice and comment even if it is kept within the agency and thereby exempted from the Bulletin's definition. Similarly, the definition of "significant guidance document" (though not the general definition of "guidance document") is limited to those "disseminated to regulated entities or to the general public," and "[d]issemination does not include distribution limited to government employees." If it affects specific rights

continued on next page

and obligations of the public, a document held close to the agency's vest can amount to the sort of "secret law" that was so widely condemned in the years leading up to the APA and should be opened to public notice and comment.

Good Guidance Practices

As mentioned above, the Bulletin's mandatory strictures have a narrow scope, falling as they do only upon those guidances that qualify as "significant." But its "Good Guidance Practices," as the preambular language of the Bulletin states, "set forth general policies and procedures for developing, issuing and using guidance documents. . . . All offices in an agency should follow these policies and procedures."

The "Basic Agency Standards for Significant Guidance Documents" are set forth in the operative text of the Bulletin. Each agency shall have written procedures for approval of the documents by appropriate senior officials. Each document shall contain, among other details: identification of the activity to which and persons to whom it applies; notation of the date and docket number of the document; citation of the statute or regulation it relates to; and identification of previous documents that it may replace. The document may not include mandatory language such as "shall" or "require" except under limited conditions. The agency shall maintain on its website a list of significant guidance documents, with links to each document, and a means for the public to comment electronically and to request issuance or modification of such documents.

Also, "[a]gency employees should not depart from significant guidance documents without appropriate justification and supervisory concurrence." If the document affects private rights and obligations, unvarying routine application by agency employees can amount to binding effect. But the agency can avoid notice-and-comment requirements if it treats the document as tentative and allows proposal of alternative policies to be considered at an appropriately high agency level. The Bulletin very helpfully permits the use of mandatory language if "the language is addressed to agency staff and will not foreclose agency consideration of positions advanced by affected private parties." One might wish that this language had been included in the preamble and directed to all guidances, not just significant ones. The preamble does offer a suggested form of disclaimer, which also might valuably be considered for use with any guidance. The disclaimer declares that the guidance represents the agency's current thinking, that it does not confer or create rights or bind the public, and that "you can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations" and may discuss an alternative approach with appropriate agency staff. Observance of the terms of such a disclaimer should largely avert concern about the improper use of guidances to bind the public.

Economically Significant Guidance Documents

Guidance documents "that may reasonably be anticipated to lead to an

annual effect on the economy of \$100-million or more or adversely affect in a material way the economy or a sector of the economy" must undergo further procedures. (This definition excludes "guidance documents on Federal expenditures and receipts," although those guidances may still qualify as "significant guidance documents" and be subject to the procedures therefor.) The draft of any such guidance must be announced in the Federal Register, posted on the Internet, and made publicly available in hard copy. The agency must invite public comment, and then prepare and post on its website what the preamble calls a "robust response-to-comments document."

Obviously, these requirements come close to those of APA § 553's notice-and-comment structure, but "this Bulletin in no way alters (nor is it intended to interpret) the APA requirements for legislative rules under 5 U.S.C. § 553." Presumably, the Bulletin would catch pronouncements—that a substance is unhealthy, perhaps, or one like the HHS/USDA Dietary Guidelines cited in the preamble – which the agency regards as unsuitable for issuance as regulations under § 553. The preamble also instances a guidance offering "fast track treatment for a particular narrow form of behavior but subject[ing] other behavior to a burdensome application process with uncertain likelihood of success." In some situations, though, such a guidance could be regarded by the courts as having practical binding effect and therefore needing notice and comment. ○

MAKE YOUR OPINION COUNT

The Section values the input of all its members. Make your opinion count. Contact us at knightk@staff.abanet.org. Also, please let us know how we can help you get more involved with Section activities.

Judicial Review of Agency Noncompliance with Public Land Manuals

By Robert L. Fischman*

A large body of literature addresses the circumstances under which federal agencies must employ APA § 553 procedures in order to make their policies binding on private parties. However, recent developments present a converse question: having gone through the notice-and-comment procedure, are the resulting policies and interpretations binding on agencies? Even if short of binding, what role should such policies play in judicial review of agency non-compliance with its manuals.

Public land manuals generally need not go through informal rulemaking because they fall under the “public property” exception of APA § 553(a). Some public land statutes, such as the National Forest Management Act, waive the exception and affirmatively require informal rulemaking for certain matters. For the vast majority of resource management guidance, notice-and-comment is not required for another reason—agency manual provisions typically are interpretive rules, rather than legislative rules. Interpretive rules state what the agency thinks a statute means, in contrast to legislative rules, which create new rights or duties. Though the APA does not require the notice-and-comment procedure for such rules, neither does it prohibit the practice.

In public land administration, where Congress typically provides vague objectives with few substantive criteria, manuals guiding how agencies should manage natural resources have long played an important role. The predecessor to the Forest Service Manual, the

“Use Book,” dates back to 1905. But recent years have seen the controversy over agency public land manuals increase. First, more manual revisions now go through notice-and-comment rulemaking. This has promoted greater public involvement and hence investment in the content of manuals. Second, a controversial 2005 draft revision of the National Park Service (NPS) “Management Policies” manual attracted national media attention and heightened sensitivity about the legal status of manuals. Third, the U.S. Fish and Wildlife Service (FWS) promulgated 2006 manual provisions with novel disclaimers of intent for judicial enforceability. And, fourth, in 2006 the D.C. Circuit reversed its 2000 determination that the “Management Policies” provisions are binding.

I. Do Manuals Directly Bind Agencies?

Courts deciding whether manuals are binding look at both substantive and procedural aspects of the administrative material. The substantive dimension concerns whether the content of a manual establishes duties an agency must meet through particular standards, methods, and mandatory language. Directives that are imprecise or written in discretionary terms will not bind agencies. The procedural dimension is the manner in which the agency promulgates the manual provision.

The majority of courts that examine the question closely find agency manuals to be non-binding, internal guidance unless some special circumstance raises the legal status of the policy. The most common special circumstance is promulgation under the notice-and-comment procedure. A rule of thumb for predicting the outcome of cases is that notice-and-comment procedure corresponds with binding status. In general, manual provisions are not promulgated

under APA § 553 procedures, but the practice is becoming more common.

In 2006, the D.C. Circuit held that the NPS “Management Policies” manual is not binding on the agency. As the latest word from the nation’s preeminent administrative law court, *Wilderness Society v. Norton*, 434 F.3d 584, (D.C. Cir. 2006), is particularly significant because it contains an extended analysis of the issue. The case involved policies that the Park Service did not promulgate under notice-and-comment procedures. In that respect, the outcome is not surprising. But, the court’s analysis raises some difficult questions about the role of manuals.

Wilderness Society dealt with a challenge to the NPS’ failure to create wilderness management plans for several parks. No statute compels the creation of these plans. But the “Management Policies” stated that each relevant park “will develop and maintain” the plans. 434 F.3d at 594. In considering whether manual or policy provisions bind resource management agencies, the opinion purported to examine two issues: the effects of the agency promulgation and the intent of the agency. But a close reading reveals that it actually considers four factors—publication and procedure, binding content, intent, and congressional mandate—which all have roots in other public land management policy cases. Here, then, are the factors courts consider in determining whether to bind a public land agency to its manual.

a. Publication and procedure.

The first factor looks at where the material is published and whether it is promulgated in conformance with APA informal rulemaking. The closer a policy’s publication and procedure comes to the standards for legislative rules, the

continued on next page

* Professor, Indiana University School of Law—Bloomington. An extended version of this essay appears as Part IV of Robert L. Fischman, *From Words to Action: The Impact and Legal Status of the 2006 National Wildlife Refuge System Management Policies*, 26 STAN. ENVTL. L.J. 77 (2007).

more likely it will bind an agency. In recent times, agencies have generally promulgated significant manual provisions through informal rulemaking procedures. For instance, Forest Service manual provisions involving a “substantial public interest or controversy” go through notice-and-comment. 36 C.F.R. § 216.6.

Wilderness Society v. Norton noted the importance not simply of employing the notice-and-comment process but also of publishing a final version in the Federal Register and codification in the Code of Federal Regulations. The court regarded the failure to codify the policy in the C.F.R. as signifying an intention to make a general policy, not a binding rule.

Unfortunately, the D.C. Circuit appears to confuse two different issues here: promulgation procedure and the standard for including a rule in the C.F.R. The first issue is the effect of a past procedure on subsequent agency behavior. The notice-and-comment process engages the public and fully vets the merits of a policy. Employing section 553 procedure ought to limit agency discretion in exchange for the attention of the public and *Chevron* deference. This is the implicit trade-off reflected in the predictive rule of thumb. But, it is a separate issue from the standard for including a rule in the C.F.R., which turns on whether an agency statement prescribes a penalty or course of conduct; confers a right, privilege, authority, or immunity; or imposes an obligation relevant to an open-ended class of the public. 1 C.F.R. § 1.1. The procedures under which a policy should bind an agency should not turn on a codification standard that hinges on the policy’s effect on private parties.

b. Binding content.

The second factor used by courts to determine the binding effect of policies is whether the manual provisions employ generally advisory and policy-oriented language. In order to be binding on the agency, the policy should “prescribe substantive rules—not interpretive rules, general statements of policy or rules of agency organization, procedure or practice.” *W. Radio Serv. v. Espy*, 79 F.3d 896, 901 (9th Cir. 1996). A substantive rule is

one that would, according to the D.C. Circuit, have a binding effect on private parties or on the agency. Thus, the standard for whether a rule binds an agency returns, via inquiry into whether it is “substantive,” to ask whether the rule binds a private party or the agency. The first question is not the subject of this particular controversy. The second is, but employs circular logic to ask whether a policy establishes a substantive rule as a means of determining whether an agency should be bound by the policy.

The use of the word “will” (or “should”), rather than unambiguous terms such as “shall” or “may” to indicate either binding intent or discretion, respectively, is a characteristic shared by many public land manual provisions. It raises an issue of agency intent to compel rather than to allow certain actions. Different courts, using different formulations of this factor in the test to determine whether an agency is bound by a manual provision, might fairly arrive at different conclusions, as courts do when interpreting these words in contracts.

c. Intent.

The third factor is agency intent. If an agency states that it means to circumscribe its own discretion through manual guidance, courts are apt to hold the agency to its word. Unfortunately, agencies often send mixed messages in stating their intent. That is the case with the 2006 FWS Refuge System policies which, as manual provisions, are intended to bind refuge managers but were promulgated with disclaimers seeking to prevent judicial enforcement in the face of agency noncompliance.

The NPS “Management Policies” stated that “[a]dherence by NPS employees to policy is mandatory unless specifically waived or modified by the Secretary, the Assistant Secretary for Fish and Wildlife and Parks, or the Director.” In 2000, the D.C. Circuit found that statement sufficient to constitute requisite intent to bind the Park Service, *Davis v. Latschar*, 202 F.3d 359, 366 (D.C. Cir. 2000), but then reached the opposite conclusion in *Wilderness Society*. The 2000 decision focused on the “mandatory” aspect of the provision, while the

2006 decision focused on the reservation of discretion on the part of political appointees to waive the policy. In neither of the cases did the higher agency officials invoke a waiver.

The FWS manual “contains the standing and continuing directives of the Service with which Service employees *must* comply. It has regulatory force and effect within the Service. . . . It establishes the requirements and procedures for employees to follow in carrying out the Service’s authorities, responsibilities, and activities.” 010 FSM § 1.4(B) (emphasis added). Therefore, absent any contrary indications in specific provisions, the agency intent factor should lead a court to find the manual policy provisions binding.

However, the FWS promulgated the 2006 policies with prefatory disclaimers in the Federal Register. The boilerplate disclaimer states the policy “is intended to improve the internal management of the Service, and it is not intended to, and does not, create any [judicially enforceable] right or benefit, substantive or procedural.” 71 Fed. Reg. 36,404. The disclaimer’s wording tracks closely the common disclaimer of judicial enforcement in executive orders. Its use in manual promulgations, however, is novel. The disclaimer does not abrogate the mandatory language of the FWS manual that binds agency officials to manual policies. Rather, the disclaimer attempts to deal only with outside enforcement of the terms of the manual to the FWS. The disclaimer expresses an intent about the agency’s susceptibility to judicial review of its decisions. It does not disclaim the manual’s statement that employees are bound by the terms of manual policy. As to the disclaimer of judicial review, it seems unlikely that an agency, through a Federal Register statement, can override the statutory rights accorded in the APA. In this respect, the disclaimer is different from those in executive orders creating policies that are not part of legislative frameworks.

d. Congressional mandate.

The fourth factor is whether the policy emanates directly from legislation. The two cases discussing this factor as a significant component of their decisions

found no basis to force an agency to comply with a policy requirement if the requirement was not mentioned in a statute. No statute mentions the special management plans for wilderness-quality lands discussed in the policy at the center of the *Wilderness Society* dispute. Similarly, *McGrail & Rowley v. Babbitt*, 986 F.Supp. 1386, 1394 (S.D. Fla. 1997), attached some significance to the absence of any reference to the FWS manual, generally, in legislation or existing rules. The greatest uncertainty in this factor is how direct the legislative connection must be.

II. Do Manuals Restrict Inconsistent Agency Behavior?

Even if manuals are not binding, they still may serve as a basis for judicial review. For notice-and-comment rules, courts regard the APA procedure as a kind of ratchet. Once an agency has engaged the public through the process, it is obliged to follow the result until it reverses itself employing the same process. This is the underlying principle of *Motor Vehicle Manufacturers Association v. State Farm*, 463 U.S. 29 (1983).

The *State Farm* Court rejected the Reagan administration's argument that an agency could deregulate more easily than it could regulate in the first place. The administration argued, in other words, that it could revoke a rule under the same low standard of review that a court would employ to review refusal to promulgate in the first place. The Court found that revocation of a rule is different from an initial decision to forego promulgating a rule. An agency does not have a very high hurdle to justify failure to promulgate (or, interpret) a rule—in fact, such a decision is close to non-reviewable. But, having established an

agency position or interpretation, an agency faces a higher standard to justify reversal.

Under the *State Farm* rationale, an agency faces a higher burden to explain its variance from a notice-and-comment promulgated policy than it would a decision not to make an official interpretation in the first place. Even if a court refuses to enforce the terms of a manual policy, they may indirectly restrict land management through the APA's general standard of judicial review. A court may find an unexplained or insufficiently supported departure from manual provisions arbitrary and capricious.

Moreover, agencies may receive *Chevron* deference under the *Mead* test for notice-and-comment promulgated policies, especially those that interpret public land legislation. But, this comes at the price of binding the agency to its published determinations. If courts will not bind agencies to their manual interpretations, then courts should refuse to grant *Chevron* deference to the definitions and interpretations in the policies.

III. Conclusion

Courts deciding whether a policy or interpretation binds an agency ought to focus on the procedure through which the provision was vetted. The presence or absence of notice-and-comment has the merit of being easy to determine, where the substantive nature of the promulgated policy can be difficult to pin down precisely. Unfortunately, even when concerning itself with procedure, the *Wilderness Society* opinion goes beyond the promulgation to ask whether the outcome is codified in the C.F.R. Alas, this is a back-door invitation to reconsider the substantive nature of the policy

because the test for codification relates to substantive attributes: i.e., whether the policy confers a right, privilege, authority, immunity, or obligation on private parties. Most manual provisions are appropriately excluded from the C.F.R. because they do not intend to establish a standard of behavior for private parties. That determination should have no bearing on whether the policies were properly promulgated to bind the public agency.

Wilderness Society concluded that binding the Park Service to follow its land management policies would “chill efforts by top agency officials to gain control over their bureaucratic charges through internal directives.” 434 F.3d at 596. On the facts, the court's conclusion seems evidently wrong: the NPS “Management Policies” explicitly allowed top agency officials to waive provisions without needing to justify their actions. Contrary to the D.C. Circuit's reasoning, officials may find it worthwhile to make the drawn-out effort to promulgate policy only if there is some assurance that the payoff will be something that binds successors absent a waiver or formal policy reversal.

Moreover, incentives for agency officials ought to be only part of the calculus in determining what is good administrative law. Another consideration is the incentive for citizen involvement. One would expect people to contribute less time and energy to policymaking when the final result is merely discretionary for the agency. Binding the agency vindicates public investment in the notice-and-comment process. It also helps resource managers resist powerful local and long-standing interests that conflict with national agency objectives. ○

**NEED SOME
CLE HOURS?**

Visit the Section's Website at www.abanet.org/adminlaw and click on ONLINE CLE for access to Section programs at WestLegalEdcenter



2007 Spring Meeting

May 18–20, 2007

The Driskill Hotel ★ Austin, TX



Built in 1886...as the showplace of a cattle baron,
The Driskill Hotel in Austin, Texas stands as a landmark of Texas hospitality.



Dear Colleagues:

The ABA Administrative Law Section will convene in May 2007 in Austin, Texas, to conduct important Section business as well as provide educational programs and an insider's look at the administrative and regulatory process. Austin is full of excitement and provides a multitude of activities that showcase its diverse cultural and national history. We look forward to seeing you in Austin.

Daniel E. Troy, *Section Chair*
Sabine Romero, *Meeting Chair*

GENERAL INFORMATION

Programs and Committee Meetings: The program chair for the meeting is Sabine Romero. Please contact Sabine via email at sabineromero@hotmail.com to discuss organizing a program. If you would like to organize a committee meeting please contact Jenny Abreu in the Section office at 202-662-1528 or at abreuj@staff.abanet.org.

The Driskill Hotel, 604 Brazos Street, Austin, TX: *This is the University of Texas graduation weekend.* Rooms will go quickly. The nightly rate is \$245 per night, single/double, plus applicable tax and daily per person gratuity. The rate will be honored for two days prior and two days after the meeting. Please call and make your reservation early to ensure your best selection: 1-800-252-9367. When calling request the ABA Administrative Law Conference rate. If you call between 7pm CST or before 7am CST, ask to be connected with reservations. Please be sure to leave a voice message stating that you are with the ABA, that you would like to make reservations for an upcoming meeting and would like a call back. The special meeting rate expires on April 18, 2007. Regular rates during this season range from \$300's to upper \$400's per night.

Visiting Austin: "This is a city with a heart and with a soul. Cosmopolitan, yet unpretentious. Thriving cultural scene and vibrant nightlife. High-tech, low-key. Big city, college town. Quirky and far from ordinary, it's the kind of place where you check your worries at the city limits sign, trade in suits for something a bit more casual and prepare for experiences you'll find only in Austin." The Section will be providing further information on various tours, meanwhile you may also peruse information on your own at <http://www.austintexas.org>.

TENTATIVE SCHEDULE

FRIDAY, MAY 18, 2007

Time	Title
12:30pm – 1:15pm	Birthright Citizenship and the Fourteenth Amendment
1:30pm – 2:45pm	Redistricting
3:00pm – 4:30pm	Report to POTUS – Roundtable Discussion
5:30pm – 7:00pm	Reception – Terrace 59
7:00pm – 9:00pm	Dine-Around- Warehouse District
9:15pm	Chairman's Hospitality – Cattle Baron Suite

SATURDAY, MAY 19, 2007

Time	Title
8:00am – 9:00am	Section Continental Breakfast
9:00am – 10:30am	Section Council Meeting
10:45am – Noon	Intersecting the Rule of Law and Administrative Law
12:15pm – 1:45pm	Publications Committee Meeting
Afternoon	Optional Tours/Activities
6:30pm – 8:00pm	Dinner at World Famous Stubbs BBQ
8:00pm – 10:00pm	Sixth Street Crawl
10:00pm	Chairman's Hospitality Suite – Cattle Baron Suite

SUNDAY, MAY 20, 2007

Time	Title
8:00am – 9:00am	Section Continental Breakfast
9:00am – Noon	Section Council Meeting

Visit www.abanet.org/adminlaw for program updates.

Direct questions to Jenny Abreu via email at abreuj@abanet.org or 202-662-1528.

By Robin Kundis Craig*

Statutes of Limitation and Administrative Proceedings

In the absence of clear indications to the contrary, “actions” and “complaints” refer only to court proceedings, not to administrative enforcement actions, the Supreme Court held in *BP American Production Co. v. Burton*, — U.S. —, 127 S. Ct. 638 (Dec. 11, 2006). More specifically, in a 7–0 decision authored by Justice Alito (Chief Justice Roberts and Justice Breyer did not participate), the Court held that the six-year statute of limitations in 28 U.S.C. § 2415(a) did *not* apply to the Minerals Management Service’s (MMS’s) administrative royalty payment orders regarding pre-September 1, 1996, oil and gas production on non-Indian federal lands.

The statute of limitations in § 2415(a) states that “every *action* for money damages brought by the United States . . . founded upon any contract . . . shall be barred unless the *complaint* is filed within six years after the right of action accrues or within one year after final decisions have been rendered in applicable administrative proceedings required by contract or by law, whichever is later” (emphasis added). In 1997, the MMS had issued royalty payment orders to BP’s predecessor Amoco regarding oil and gas production on federal lands from January 1989 through December 1996. Amoco and then BP argued that these orders were barred by the six-year statute of limitations in § 2415(a). Both the district court and the U.S. Court of Appeals for the D.C. Circuit held that the statute of limitations did *not* bar the MMS’s administrative orders, and the Supreme Court agreed.

The Supreme Court viewed its decision as primarily one of statutory construction. Under its plain meaning analysis, it concluded that “[t]he key terms in this provision – ‘action’ and ‘complaint’—are ordinarily used in connection with judicial, not administrative, proceedings.” *BP American*, 127 S. Ct. at 643. Moreover, “[n]othing in the language of § 2415(a) suggests that Congress intended these terms to apply more broadly to administrative proceedings,” especially given the fact that § 2415(a) specifically refers to both general accrual and the termination of administrative proceedings. *Id.* at 644.

The Court then expanded its interpretation by looking at “action” and “complaint” individually. It noted that when Congress intends the word “action” to refer to administrative proceedings, it tends to qualify that word—“administrative action,” “civil or administrative actions,” “administrative enforcement actions”—whereas § 2415(a), in contrast, used “action” standing alone, which refers to court proceedings. *Id.* Similarly, “[t]he occasional use of the term [‘complaint’] to

describe certain administrative filings does not alter its primary meaning, which concerns the initiation of ‘a civil action.’” *Id.* at 646 (quoting *Black’s Law Dictionary* 356). This limitation was especially appropriate for the MMS’s royalty payment orders, because those orders function as final administrative enforcement orders, not as the initiation of enforcement proceedings. *Id.*

The Supreme Court reinforced its interpretation of the plain meaning of § 2415(a) with “the rule that statutes of limitation are construed narrowly against the government.” *Id.* (citation omitted). “A corollary of this rule is that when the sovereign elects to subject itself to a statute of limitations, the sovereign is given the benefit of the doubt if the scope of the statute is ambiguous.” *Id.*

In light of the statute’s plain meaning and the sovereignty canon for statutes of limitation, the Court rejected all of BP’s structural and policy arguments in favor of applying the six-year statute of limitations to the MMS’s administrative payment orders—subsections rendered superfluous, peculiarities in recordkeeping requirements, and frustration of the statute’s purpose of providing repose. *Id.* at 646–49. Instead, the Court emphasized that Congress could have amended the relevant statutes so that they clearly applied to administrative actions, that BP’s arguments “must be considered in light of the traditional rule exempting proceedings brought by the sovereign from any time bar,” and that the focus of the Court’s inquiry “is simply how far Congress meant to go when it enacted the statute of limitations in question.” *Id.* at 649. As a result, the Court upheld the MMS’s right to seek the additional royalty payments for the pre-September 1, 1996, oil and gas production.

The *exact* holding of *BP American* may be limited in import: Congress amended the relevant minerals leasing statutes in 1996 to impose seven-year statutes of limitation on *both* judicial and administrative royalty payment proceedings for post-September 1, 1996, oil and gas production. However, the underlying logic and interpretive analysis of *BP American* establishes a clear presumption against the application of general statutes of limitation to federal administrative enforcement proceedings, counseling administrative lawyers to find statutes that clearly apply to administrative proceedings.

Due Process

In a 5–4 decision authored by Justice Breyer (with the unusual alliance of Justices Stevens, Ginsburg, Thomas, and Scalia dissenting), the Supreme Court held in *Philip Morris USA v. Williams*, — U.S. —, — S. Ct. —, 2007 WL 505781 (Feb. 20, 2007), that the Due Process Clauses of the Fifth and Fourteenth Amendments prohibit juries from imposing punitive damages on civil defendants to punish those defendants for injuries to third parties not represented in the litigation. Punitive damages, the majority noted, can undermine notions of due process in several ways—by depriving defendants of fair notice of the range of punishment available in response to

* Attorneys’ Title Insurance Fund Professor of Law, Florida State University College of Law, Tallahassee, Florida. The author may be reached by e-mail at rcraig@law.fsu.edu.

certain conduct, by threatening arbitrary punishments, and by allowing one state or one jury to impose its policy preferences unfairly. *Id.* at *4.

Using punitive damages to punish defendants for injuring third parties similarly offends the Due Process Clauses. “For one thing, the Due Process Clause prohibits a State from punishing an individual without first providing that individual with ‘an opportunity to present every available defense,’” and that opportunity cannot exist if the defendant is to be punished for injuries to nonparties, against whom the defendant cannot establish the validity of the injury or the existence of any defense. *Id.* at *5 (citation omitted). “For another, to permit punishment for injuring a nonparty victim would add a near standardless dimension to the punitive damages equation.” *Id.* “Finally, we can find no authority supporting the use of punitive damages awards for the purpose of punishing a defendant for harming others . . .” *Id.*

The majority did acknowledge that jurors *could* properly consider injuries to third parties when assessing that reprehensibility of the defendant’s conduct, another prong of the punitive damages assessment. *Id.* at *5–*6. However, because the Oregon Supreme Court did not clearly distinguish the proper

from the improper uses of third-party injuries, the U.S. Supreme Court remanded the punitive damages award at issue for reconsideration.

Justice Stevens, writing in dissent, acknowledged that “[t]he Due Process Clause of the Fourteenth Amendment imposes both substantive and procedural constraints on the power of States to impose punitive damages on tortfeasors.” *Id.* at *8 (J. Stevens, dissenting). However, he considered the third-party injury limitation to be “novel” and saw “no reason why an interest in punishing a wrongdoer ‘for harming persons who are not before the court’ . . . should not be taken into consideration when assessing the appropriate sanction for reprehensible conduct.” *Id.* (J. Stevens, dissenting). Justice Thomas, in turn, wrote separately to emphasize that due process considerations should not constrain the size of punitive damages awards, either. *Id.* at *9 (J. Thomas, dissenting). Finally, Justice Ginsburg, writing for herself, Justice Scalia, and Justice Thomas argued that the Oregon Supreme Court had properly applied the U.S. Supreme Court’s rulings on punitive damages and upheld the award of punitive damages in order to punish the defendant’s reprehensibility. *Id.* at *10–*11 (J. Ginsburg, dissenting). ○

The Case for Federalizing Mandated Health Benefits *continued from page 3*

states currently play due to ERISA preemption, this does not represent a significant loss. And it is true that federal regulation would result in a greater regulatory burden than our current system, because it would prevent purchasers from being able to opt out of the system by self-insuring. However, a regulatory system that applies equally and fairly is a better system than one that allows the biggest players to opt out, even if it does potentially increase the regulatory burden on those who previously enjoyed special treatment.

A counter argument could be made that this is not a preferable outcome if it results in lower coverage rates due to increased cost. I agree that such an outcome would be cause for significant concern. However, under a regulatory system that applies equally to all, there should be greater incentive for both Congress and large employers to lobby for change (that is, if federal mandates are

adversely affecting coverage rates, the big players should be incentivized to take political action to lessen the regulatory burden). Under our current system, the most powerful players (large employers) have no reason to engage in the state mandated benefit debate.

Conclusion

Critics are right to see serious flaws in our current system of health care regulation, particularly with respect to state mandated benefit laws. The disparate treatment of insured versus self-insured plans is difficult, if not impossible, to justify, particularly given the disadvantageous position in which it puts small employers and individual purchasers. The answer, however, does not lie in deregulation. There are very good reasons for the government to mandate that health insurance policies include certain benefits. Without benefit mandates, individuals with certain conditions may

be unable to receive effective health insurance coverage. We may be disappointed with how states currently legislate these benefits, but the truth remains that benefit mandates can serve very important purposes. As a result, the best reform option for mandated benefit laws is for the federal government to (1) preempt the ability of the states to regulate the content of health insurance policies and (2) enact appropriate federal-level benefit mandates. Not only would this reform preserve the policy functions that mandated benefits serve, but it would also eliminate the preferential treatment that self-insured plans currently enjoy. While federalizing mandated benefits would not solve all of America’s health care problems, it would represent an incremental improvement over the status quo and, unlike deregulation, would not make our current health care problems even worse by further stratifying risk. ○

By William S. Jordan III*

9th Circuit Holds Draft Policy Statement Reviewable as Final Agency Action

Over a vociferous dissent by Judge Kozinski, the Ninth Circuit held that an agency's draft policy statement is reviewable as final agency action. If widely followed, the decision threatens ever deeper intrusion into agency management decisions. It would also create a significant disincentive for agencies that might otherwise issue draft or tentative policy positions when they are not ready to initiate rulemaking proceedings.

The Animal Welfare Act requires the U.S. Department of Agriculture to promulgate regulations requiring that zoos and other regulated facilities provide "a physical environment adequate to promote the psychological well-being of primates." In 1991, the USDA adopted a legislative rule requiring that nonhuman primates be housed in compliance with "currently accepted professional standards." Responding to a challenge by the Animal Legal Defense Fund (ALDF), the D.C. Circuit in 2000 upheld the regulation, ruling that the statute did not require greater specificity than provided by the regulation.

Meanwhile, in 1999 the USDA issued a report concluding that both inspectors and regulated entities needed more guidance and that many facilities provided stimulus-poor environments. The report was accompanied by a Draft Policy that included a safe harbor provision through which regulated entities could be certain of compliance. The USDA sought public comment on the Draft Policy, but it did not purport to be proposing the policy as a legislative rule.

In December 2002 and March 2003, a USDA official orally declared that the agency did not intend to go forward with the Draft Policy. ALDF then sued on the theory that these declarations constituted final agency action—a final decision not to proceed. In *Animal Legal Defense Fund v. Veneman*, 469 F.3d 826 (9th Cir. 2006), the Ninth Circuit agreed.

Two aspects of the decision are particularly noteworthy, the first relates to standing, the second to finality. As to standing, the court said that review held sufficient promise of redress because requiring the agency to explain its failure to adopt the Draft Policy (which is all the court could actually do) could influence the agency in a way that would achieve better compliance. The majority considered the situation comparable to NEPA litigation, under which standing depends upon the increased likelihood of environmental protection, not upon any certainty that it will be achieved. Judge Kozinski argued in dissent that the NEPA decisions depended upon the fact that NEPA imposed certain procedures with the ultimate goal of enhancing environmental protection, thereby enhancing the likelihood of redress. The Animal Welfare Act imposed no comparable procedures.

* C. Blake McDowell Professor of Law, The University of Akron School of Law; Council Member; Chair Judicial Review Committee; and Contributing Editor.

As to finality, the majority held that the declared decision not to adopt the Draft Policy was the "consummation" required by *Bennett v. Spear*. It then held that the decision not to adopt the policy was reviewable because (1) a decision to adopt it would have been reviewable, and (2) the decision not to adopt affected legal rights and obligations because it left the status quo in place. As Judge Kozinski explains, none of this makes much sense. The majority cites challenges to refusal to list species as endangered, for example, but the analogy is inappropriate because a listing would provide certain protection, while adoption of the Draft Policy and safe harbor would not assure any enhanced compliance or enforcement. Judge Kozinski responded that *Heckler v. Chaney* precludes review. The refusal to adopt the Draft Policy reflected the agency's exercise of prosecutorial discretion, which could have been based several unreviewable considerations, including resource limitations and changes in policy. Moreover, Judge Kozinski argued that the refusal to finalize the Draft Policy was not consummation of the agency's decisionmaking process because the agency was continuing to develop best management practices for the handling of nonhuman primates. Bottom line: consider this case if you want to sue an agency for refusing to do something that it once mentioned as a possibility. You might get in the door, but you probably shouldn't.

9th Circuit Grants Chevron Deference to Notice-&-Comment Policy Statement

In *Northwest Ecosystem Alliance v. United States Fish and Wildlife Service*, 2007 WL 286581 (9th Cir., Feb. 2, 2007), the Alliance challenged the agency's refusal to list the western gray squirrel as endangered in a "distinct population segment" in the State of Washington. The Endangered Species Act requires the listing not only of a species threatened with extinction, but also of a "distinct population segment" of a species that is otherwise not threatened. In this case, the squirrel existed in healthy numbers in California and Oregon, but its numbers were apparently in decline in Washington. The question was whether the Washington squirrels were sufficiently distinct from their southern relatives.

In 1996, the USFS issued the Distinct Population Segment Policy Statement (DPS Policy), in which it set forth two factors to be considered in answering this sort of question: (1) the "[d]iscreteness of the population segment in relation to the remainder of the species to which it belongs," and (2) the "significance of the population segment to the species to which it belongs." The agency had considered adopting the policy as a legislative rule, but it had declined to do so, issuing only a policy statement. Of particular interest, the DPS Policy had been issued through a notice-and-comment process required by the Endangered Species Act for such guidelines even though it had not been issued as a legislative rule.

After initially proposing to list the Washington population, the agency ultimately declined to do so. Although the popula-

tion was sufficiently discrete, it was not “significant to the taxon,” as required by the DPS Policy. The Alliance argued that the distinct requirement of “significant to the taxon” violated the ESA. Holding the term “distinct population segment” to be ambiguous, the court then held that the DPS Policy was entitled to *Chevron* deference despite the fact that it was not a legislative rule. Applying the principles of *U.S. v. Mead*, the court held that three considerations dictated that *Chevron* deference should apply. First, the ESA notice-and-comment requirement provided “procedural rigors” comparable to the informal rulemaking process that would trigger *Chevron* under *Mead*. Second, the ESA specifically required the agency to issue such guidelines. Third, “the DPS Policy has [n]ever been treated (by the Service or parties presenting petitions to list species) as anything other than legally binding,” so it had the requisite “force of law.”

The decision is peculiar only because an agency decision that had the procedural trappings of a rulemaking and was treated as legally binding was not, strictly speaking, a legislative rule. Perhaps the agency had sought to avoid many of the other burdens on the rulemaking process, such as Regulatory Impact Analysis, and the like. The lesson of this decision seems to be that if an agency issuance is required by statute to go through a process that looks pretty much like rulemaking, *Chevron* deference is likely. Since we can expect many more guidance documents to go through a similar process as a result of Executive Order 13422, the next question will be whether presidential imposition of such procedures will give rise to *Chevron* deference.

One further point is worth noting. The Alliance complained that the agency had improperly considered a post-enactment Senate Committee report expressing concern that the “discrete population segment” concept might be abused, and urging that it be used only sparingly. Although such post-enactment reports are typically of little or no value in statutory interpretation, the court emphasized that it was applying the “deferential *Chevron* standard.” Since it is appropriate for unelected judges to consider the views of elected representatives, and since there was no obvious tension between the report and the statutory text, it was permissible for the Secretary to rely in part on the report. The court does not explain why an agency may rely upon such post-enactment material, when generally courts should not. Perhaps it was really a matter of harmless error.

9th Circuit Rejects Agency Funding Decision Based on Committee Reports

After the furor over congressional “earmarks” in recent years, perhaps it is appropriate that a court would strike down an agency decision based solely upon congressional committee directives that are quite comparable to earmarks. Earmarks frequently are not specifically included in appropriations bills, but identified in accompanying reports. That is what happened

in *Northwest Environmental Defense Center v. Bonneville Power Administration*, 2007 WL 163102 (9th Cir., Jan. 24, 2007). In response to declining salmon and steelhead populations in the Columbia River, Congress enacted the Northwest Power Planning and Conservation Act of 1980. The Act created the Northwest Power and Conservation Council and directed the Bonneville Power Administration to “to use its authority in a manner consistent with the programs developed by the Council.” At the Council’s direction, the BPA in 1987 began funding the Fish Passage Center (FPC), which provides information and technical assistance to various actors concerned with protecting the fish populations in question. The FPC was implemented through a contract with the Pacific States Marine Fisheries Commission

All went swimmingly until 2005, when a Senate Appropriations Subcommittee and a Conference Committee each issued reports stating that BPA “may make no new obligations in support of the Fish Passage Center.” The reports urged that the functions be transferred to area universities or other entities capable of carrying out the FPC’s functions. The BPA then issued a program solicitation and ultimately contracted with two private firms to carry out two distinct aspects of the FPC’s operations.

Various challengers sought review, arguing that BPA’s actions violated the Northwest Power Act. As to reviewability, the BPA conceded that the new contracts constituted final agency action, but they argued that there was no basis for standing because a court could not provide redress. This argument was based upon the proposition that the agency had merely switched contractors, and a court could not normally order an agency to contract with any particular party. After distinguishing the cases cited by the BPA as involving judicial intervention into contracts between private parties, the court used very broad language in holding that it had the equitable authority to address a violation of law, including arbitrary and capricious behavior, in a public law controversy: “Unless Congress provides otherwise, “[c]ourts of equity may, and frequently do, go much farther both to give and withhold relief in furtherance of the public interest than they are accustomed to go when only private interests are involved.” This language seems broader than necessary since the Northwest Power Act itself mandated that the BPA act consistently with the programs developed by the Northwest Power and Conservation Council. The court’s reference to APA review would have been enough, without reference to broad equitable powers.

Reaching the merits, the court found that the BPA’s action was based entirely upon the directives in the committee reports. Given that finding, the BPA was doomed. Principles of separation of powers, as reflected in *INS v. Chada*, dictate that Congress may not act through its committees. For that reason,

continued on next page

News from the Circuits

“legislative history, untethered to text in an enacted statute, has no compulsive legal effect.” Moreover, the action conflicted with the BPA’s statutory duty to act consistently with the program created by the Council. Thus, the BPA action was contrary to law.

The action was also arbitrary and capricious because the BPA could offer no justification for its action other than the congressional report language. An agency may change a long-standing practice, but “an agency changing its course must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored, and if an agency glosses over or swerves from prior precedents without discussion it may cross the line from the tolerably terse to the intolerably mute.” With the Council still calling for funding the FPC, the BPA could not justify its action by reference to the committee reports, and it had provided no other basis for sustaining its position.

This decision is unusual in its intrusion into an agency’s contracting and allocation of funds. It might seem, at first glance, inconsistent with *Lincoln v. Vigil*, which held that the Public Health Service’s reallocation of funds was unreviewable. But the two are quite distinct. Here, the Northwest Power Act specifically required that the BPA act consistently with the wishes of the Northwest Power and Conservation Council, and the Council had sought continued funding of the FPC. The decision does not open the door to challenges to typical congressional earmarks or other reallocation of funds.

D.C. Circuit Upholds Recovery of Self-Representational FOIA Attorney Fees

In *Baker & Hostetler LLP v. U.S. Dept. of Commerce*, 473 F.3d 312 (D.C. Cir. 2006), the D.C. Circuit held that a law firm that represents itself as an FOIA claimant may recover attorney fees to the extent that it substantially prevails in the litigation. *Baker & Hostetler* represented Canadian lumber interests in connection with a long-running trade dispute. But the firm represented itself in seeking various records related to the dispute. Despite the firm’s success in obtaining many of the documents it had sought, the District Court denied recovery on the ground that a law firm representing itself is ineligible for fee recovery.

On review, the D.C. Circuit reversed based upon the FOIA’s plain language and upon a footnote in *Kay v. Ehrler*, 499 U.S.

432 (1991). The FOIA provides for recovery by all “complainants” who have “substantially prevailed.” There is no exception for those representing themselves.

In *Kay*, however, the Supreme Court held that an individual representing himself could not recover “attorney” fees under a provision for fee recovery in civil rights litigation. The Court reasoned that the term “attorney” refers to an attorney-client relationship in which an attorney provides independent, unbiased judgment to the claimant. Moreover, the court noted that the fee recovery provision was designed to “enable potential plaintiffs to obtain the assistance of competent counsel in vindicating their rights.” Thus, an individual representing himself would not qualify. This logic might apply to prevent recovery by a law firm or other organization with in-house counsel, but the Court dropped *Fn. 7*, in which it said that “an organization is not comparable to a *pro se* litigant because the organization is always represented by counsel, whether in-house or *pro bono*, and thus, there is always an attorney-client relationship.” On this basis, the D.C. Circuit held that *Baker & Hostetler* was entitled to seek fees for representing itself, joining two other circuits in its interpretation.

Judge Henderson dissented as to the issue of attorney fees. Asserting that the majority had ignored “*Kay*’s emphasis on independent judgment and ethical considerations” in denying recovery to individual lawyer-litigants, she expressed concern about the obvious self-interest involved in a law firm recovering for itself: “Absent the ‘detached perspective’ that comes from independent counsel, a law firm as an entity—as much as a lawyer-litigant—may have an interest in bringing suit if a fee-shifting statute is in effect ‘solely as a way to generate fees rather than to vindicate personal claims.’” She also noted the possibility that the law firm-claimants might be called as witnesses in cases in which they represented themselves.

Update: Abigail Alliance to be reviewed en banc.

In the Summer 2006 issue, the News reported that the D.C. Circuit had found a substantive due process right to use certain experimental cancer drugs that had passed some levels of screening but had not yet been approved by the FDA. *Abigail Alliance for Better Access to Developmental Drugs and Washington Legal Foundation v. Von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006). On November 21, 2006, the D.C. Circuit granted en banc review and vacated the judgment. 

IS YOUR
LIBRARY
COMPLETE?

Check the list of Administrative Law publications at www.ababooks.com to be sure.

Recent Articles of Interest

By Yvette Barksdale*

1. **Robert Post, *Federalism, Positive Law, And The Emergence Of The American Administrative State: Prohibition In The Taft Court Era*, 48 WM. & MARY L. REV. 1 (2006).**

This article is an “archaeological” examination of the federal administration of prohibition in the 1920s. The author argues that the prohibition era has many lessons for the development of American constitutional history, and the rise of the modern administrative state. Prohibition was the federal government’s first significant foray into regulating the ordinary details of everyday life. The battle over Prohibition raised issues of: (1) federalism (arising from the attempts of the very weak federal administrative state to enlist state law enforcement resources to Prohibition); (2) the salience of written law in a common law society; (3) erasure of the normal public/private distinction in Constitutional law since the 18th Amendment directly regulated private behavior; and (4) realignment of the Supreme Court’s ordinary conservative/liberal divide, splitting Conservatives into separate limited government, and “rule of law” wings, and causing Progressives to rethink their view of the proper role of the emerging administrative state. The article provides an in-depth detailed, historical account of the Taft Court’s legal, political, and social struggles over these and other issues. These forays presage future battles over the proper role of the administrative state in American government.

2. **Kristin E. Hickman, *Coloring Outside the Lines: Examining Treasury’s (Lack of) Compliance with Administrative Procedure Act Rulemaking Requirements*, Forthcoming, 82 NOTRE DAME L. REV. __ (2007) <http://ssrn.com/abstract=955929>.**

This article is an empirical study of the United States Treasury Department’s compliance with Administrative Procedure Act (APA) notice and comment requirements. The article studies 232 separate regulatory projects interpreting the Internal Revenue Code over a three year period (January, 2003 to December, 2006). The author, in a detailed analysis, concluded that the Treasury Department often failed to adhere to APA rulemaking requirements. Instead, the department, even in some of its most complex and controversial efforts, relied upon inapplicable interpretive, procedural and good cause exceptions to rulemaking. The author believes that the agency’s noncompliance with the APA is not willful, but rather is a byproduct of 1) the agency’s

“well-intentioned pursuit of alternative priorities,” and 2) increased agency staffing with tax attorneys who have limited administrative law experience.

3. **Kenneth A. Bamberger, *Regulation as Delegation: Private Firms, Decisionmaking and Accountability in the Administrative State*, 56 DUKE L. J. 377 (2006).**

This article argues that many problems of broad legislative delegations to administrative agencies also afflict statutory “delegations” to large corporate firms and other complex regulated entities of broad discretion to determine how best to comply with vague regulatory requirements. One example is a Sarbanes-Oxley Act provision, that requires investment advisers to adopt policies and procedures “*reasonably designed to ensure that the [adviser] vote[s] . . . in the best interest of clients.*” Despite the provisions’ vagueness, the Securities and Exchange Commission (SEC) refuses to adopt specific compliance policies. The author, using administrative accountability, “theory of the firm,” and behavioural law and economics literature, analyzes how such vague standards allow “predictable behavioural pathologies” to steer regulated firms’ compliance decisions in directions which often undermine, rather than advance, the regulations’ objectives.

4. **Cass R. Sunstein, *Willingness To Pay Versus Welfare*, Forthcoming, ____ HARV. L. AND POL’Y REV. ____ (2007), http://ssrn.com/abstract_id=959724.**

In this essay, Cass Sunstein critiques the view that under Cost-Benefit Analysis (CBA), an individual’s “willingness to pay” for a good is consistently a sound proxy for the welfare the person would receive from the good. The fit between “willingness to pay” and “welfare” is particularly problematic when assessing welfare in programs that redistribute resources from the rich to the poor. Because an extra dollar is worth more to a poor person than a rich person, such redistribution may still increase overall welfare, even if it fails Cost-Benefit Analysis, because the redistributed resources will shift to persons who more highly value them.

5. **Ellen Katz, Margaret Aisenbrey, Anna Baldwin, Emma Cheuse, Anna Weisbrodt, *Documenting Discrimination In Voting: Judicial Findings Under Section 2 Of The Voting Rights Act Since 1982*, 39 U. MICH. J.L. REFORM 643 (2006).**

This article is a description of a large empirical study of voting rights claims under Section 2 of the 1965 Voting Rights Act, which were judicially decided after passage of Section 2’s 1982 Amendments. Among other findings, the study found that voting rights plaintiffs prevailed in over 37% of the claims brought, demonstrating, the authors note, that voting rights discrimination still occurs more than 30 years after the original enactment of the Voting Rights Act.

continued on next page

* Associate Professor of Law, The John Marshall Law School, Chicago, IL; Co-Chair, Constitutional Law and Separation of Powers Committee; and Contributing Editor. These abstracts are drawn primarily from the authors’ introductions to their articles. To avoid duplication, the abstracts do not include articles from the Administrative Law Review which Administrative Law Section Members already receive.

Recent Articles of Interest

6. Preemption Colloquy: (Online journal)

Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT LAW 4 (2007), <http://www.bepress.com/jtl/vol1/iss1/art4>.

The author addresses whether Food and Drug Administration (FDA) regulation should preempt state tort laws. After first discussing current doctrine, the author shifts to institutional design, explaining why tort law and the administrative state have recently come into conflict. The author argues that regulatory preemption can be used to encourage risk disclosure and fraud prevention by manufacturers eager for regulatory preemption of state tort claims. Similarly, information from tort litigation can update regulatory information about pharmaceutical risks. The article also discusses recent litigation claiming a causal link between some antidepressant drugs and suicide.

Richard A. Epstein, *Response, Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. TORT LAW 5 (2007), <http://www.bepress.com/jtl/vol1/iss1/art5>.

Richard Epstein critiques Nagareda's position advocating regulatory preemption to encourage increased manufacturer compliance with disclosure and other regulatory requirements. Such incentives would likely result in overregulation and over-deterrence, Epstein argues. Instead of the traditional presumption against preemption, he advocates a presumption in favor of broad "field preemption" of state tort law by the grant of regulatory authority to the FDA.

7. Nicholas Bagley and Richard L. Revesz, *Centralized Oversight Of The Regulatory State*, 106 COLUM. L. REV. 1260 (2006).

The authors advocate a reconsideration of the entrenched role that centralized Office of Management and Budget (OMB) review has in regulatory decisionmaking. Centralized rulemaking is not justified as a defense against costly overregulation, the authors assert. Little academic or other analysis supports the view that that agencies have significant biases towards overregulation. Moreover, OMB review is a poorly designed weapon against any such regulatory biases, which diverts resources from the policing of regulatory rationality. The authors also contest the view that the Office of Information and Regulatory Affairs (OIRA) has any greater claim to neutrality in assessing costs and benefits of rules than the originating agencies. Instead, OIRA should devote less attention to overregulation, and more attention to interagency harmonization, such as standardized scientific guidelines for making risk assessments, particularly with respect to carcinogens, and 2) considering the distributional consequences of all regulations.

Symposia of Interest

1. ***Duke Annual Administrative Law Issue*, 56 DUKE LAW J. 1, et. seq. (2006). Articles by:** i) Matthew D. Adler, *Policy Analysis for Natural Hazards: Some Cautionary Lessons From Environmental Policy Analysis* (p. 1); ii) Ellen P. Aprill, Richard Schmalbeck, *Post-Disaster Tax Legislation: A Series of Unfortunate Events* (p. 51); iii) Ben Depoorter, *Horizontal Political Externalities: The Supply and Demand of Disaster Management* (p. 101); iv) Brandon L. Garrett, Tania Tetlow, *Criminal Justice Collapse: The Constitution After Hurricane Katrina* (p. 127); v) Douglas A. Kysar, Thomas O. McGarity, *Did NEPA Drown New Orleans? The Levees, the Blame Game, and the Hazards of Hindsight* (p. 179); and Jim Rossi, *State Executive Lawmaking in Crisis* (p. 237).

2. ***The Value Of The Vote: The 1965 Voting Rights Act And Beyond*, 49 HOW. L. J. 669, et. seq. (2006).** a) *Letter From The Editor-In-Chief*, Tamer O. Bahgat, p. 669, and b) **Articles by:** i) Christopher Edley, Jr., *Keynote Address: Reauthorization Of The Voting Rights Act*, p. 673; ii) Michael A. Nemeroff, *The Limited Role Of Campaign Finance Laws In Reducing Corruption By Elected Public Officials*, p. 687; iii) Nathaniel Persily, *Options And Strategies For Renewal Of Section 5 Of The Voting Rights Act*, p. 717; iv) Richard H. Pildes, *The Future Of Voting Rights Policy: From Anti-Discrimination To The Right To Vote*, p. 741; v) Richard L. Hasen, *The Uncertain Congressional Power To Ban State Felon Disenfranchisement Laws*, p. 767; vi) Daniel P. Tokaji, *If It's Broke, Fix It: Improving Voting Rights Act Preclearance*, p. 785.

3. **David Michaels and Neil Vidmar, Special Editors, *Sequestered Science: The Consequences of Undisclosed Knowledge*, 69-SUM LAW & CONTEMP. PROBS. 1, et. seq. (2006). Articles by:** i) David Michaels, *Foreword: Sarbanes-Oxley for Science*, p. 1; ii) Sheila Jasonoff, *Transparency in Public Science: Purposes, Reasons, Limits*, p. 21; iii) Susan Haack, *Scientific Secrecy and "Spin": The Sad, Sleazy Saga of the Trials of Remune*, p. 47; iv) Scott M. Lassman, *Transparency and Innuendo: An Alternative to Reactive Over-Disclosure*, p. 69; v) Peter Lurie and Allison Zieve, *Sometimes the Silence Can Be like the Thunder: Access to Pharmaceutical Data at the FDA*, p. 85; vi) Sidney A. Shapiro and Rena I. Steinzor, *The People's Agent: Executive Branch Secrecy and Accountability in an Age of Terrorism*, p. 99; vii) Daniel J. Givelber and Anthony Robbins, *Public Health Versus Court-Sponsored Secrecy*, p. 131; viii) James W. Conrad Jr., *Open Secrets: The Widespread Availability of Information About the Health and Environmental Effects of Chemicals*, p. 141; ix) Allen L. White, *Why We Need Global Standards for Corporate Disclosure*, p. 167.

continued on page 28

Section News & Events

Second Annual Homeland Security Law Institute a Smashing Success

By *Lynne Zusman**

The Second Annual Homeland Security Law Institute of the Administrative Law and Regulatory Practice Section built on the success of last year's inaugural Institute by drawing two hundred fifty attendees on January 18 and 19, 2007.

This year the Institute comprised nine panels of distinguished speakers and featured most prominently DHS Secretary Michael Chertoff, who delivered an outstanding address summarizing areas of growth and progress in Homeland Security in the 4-1/2 years of DHS and explaining the necessity for partnership between government and the private sector, the theme of the Institute.

Among the many issues Secretary Chertoff addressed were border security; information reform; risk management in the private sector; and the break through in biometric fingerprint technology. Secretary Chertoff spoke at length on the necessity for continued inspection of high risk containers in overseas ports and the safeguarding of chemical sites and hazardous cargo. He also discussed DHS' relationship with the Department of Defense and FEMA overhaul. Secretary Chertoff referenced the lessons learned from Y2K and asserted that US effectiveness confronting security threats has significantly matured since then.

Secretary Chertoff was introduced by Institute Co-Chair and first DHS General Counsel, the Honorable Joe D. Whitley.

Brussels Dialogue Enhances Quality of Section EU Study

By *Jim O'Reilly***

High-ranking officials and high intensity focus on draft papers about European administrative law marked an important February meeting in Brussels, Belgium, at the headquarters of the European Union. The Deputy Secretary General of the European Union and representatives from the Directorates General, the Parliament, the Secretariat and the Legal Service greeted an ABA delegation in Brussels on Feb. 1 and 2, as part of our Section's Project on the Administrative Law of the European Union.

"The meetings were very successful, and we are quite pleased with the reception our research has received," said Chief Reporter George Bermann. Bermann and Assistant

Chief Reporters Jim O'Reilly and Charles Koch are coordinating the work of dozens of contributors. The key players on the project are the U.S. Co-Reporters for lengthy studies on five specific topical areas of EU operations: rule-making, adjudication, judicial review, transparency and oversight.

Presenting their draft reports for comment, the U.S. Co-reporters heard extensive and specific suggestions for the next phase of writing and editing. Rulemaking was presented by Peter Strauss and Lucas Bergkamp, and drew very positive feedback. Michael Asimow and Lisl Dunlop spoke for the adjudication team on the first day of the two-day session. Judicial Review was presented by Ron Levin and Frank Emmert, with extensive comments by the European Commission Legal Service advocates. Tom Susman spoke for the co-reporters on Transparency, including disclosure and privacy conflicts.

The final paper on Oversight will be managed by Peter Lindseth, whose talk on oversight drew great interest from European Parliament staff members and from the Commission Legal Service and Secretariat.

Many of the arrangements were facilitated by the excellent staff of the U.S. Mission to the European Union, led by Ambassador and former Section Chair Boyden Gray. The sessions were intensely specific comments about ways in which improvements could be made in the papers; the oral dialogue fleshed out several dozen pages of written feedback and suggestions.

The evening social highlights of the program were dinners arranged by Boyden's very capable staff and a reception at the Ambassador's Residence for the EU and ABA participants.



Front row: George Bermann, Charles Koch, Ron Levin, Tom Susman, Lisl Dunlop, Michael Asimow. 2nd row: Boyden Gray, Peter Strauss, Sid Shapiro, Jim O'Reilly. 3rd row: Peter Lindseth, Frank Emmert.

continued on next page

* Co-Chair Homeland Security Law Institute, Homeland Security Committee, and Defense & National Security Committee.

** University of Cincinnati College of Law; Assistant Chief Reporter, EU Project; Former Section Chair; and Advisory Board Member, Administrative & Regulatory Law News.

Section News & Events

The Project plans to have its revised papers up on the section website for further comments, leading up to publication of the revised final papers in late summer or early fall. Please read and comment now, so that your views can be fully weighed among others' insights. The Fall 2007 Washington meeting of the Section will address our members' and EU leaders' feedback on the papers, and a possible spring 2008 session in Brussels may be coordinated with a planned session of the inter-governmental regulatory dialogue between EU officials and the U.S. Office of Information & Regulatory Affairs.

The EU Project needs the input of all Section members; we urge you to read the papers on the Section website and to communicate with the drafters, or with O'Reilly and Koch at james.oreilly@uc.edu or chkoch@wm.edu.

Council Charts Long Range Plan for Section

By Michael Asimow***

The Council of the Administrative Law and Regulatory Practice Section held a long-range planning session at the Midyear Meeting in Miami this past February. The principal topic of discussion was the Section's substantive priorities during the next several years. Key priorities identified include:

- Wrapping up the European Union project with the publication of a book;
- Adopting a model local land-use planning ordinance;
- Generating prescriptive recommendations for improving the rulemaking process (parallel to our recommendations about adjudication a few years ago);
- Playing an active role in the improvement of e-rulemaking in general and *regulations.gov* in particular;
- Developing an algorithm to help agencies decide whether to issue regulations or guidance documents;
- Formulating a set of international election standards;
- Participating in the ABA's "Rule of Law" project;
- Establishing an administrative law pro bono program; and
- Producing a letter about administrative law priorities addressed to whoever wins the 2008 presidential election.

Meeting participants expressed a desire to improve the functioning of committees by finding enthusiastic young people to serve as vice chairs, perhaps by drawing on our liaison with the Young Lawyers Division. We agreed that it was important to move vice-chairs into chair roles and to create openings by rotating long-serving chairs out.

*** Professor of Law Emeritus, UCLA Law School; Section Chair-Elect; and Advisory Board Chair of the News.

We discussed the need for a dues increase. The Section's dues (\$40 per year) are among the lowest in the ABA, and yet the Section provides three free publications to its members. The dues increase requires a bylaw amendment that will be considered at the annual meeting.

It was agreed that the Council should apply for one of the new ABA "Enterprise Grants" (which requires projects involving several sections). The possibilities include our preemption task force, the e-rulemaking project, or the international election standards project.

Finally, we discussed our quarterly meetings, particularly the fall meeting, and the need to minimize the financial losses from these meetings. This will require a stronger effort to attract sponsors and possibly higher meeting and CLE fees. We also hope to improve our legislative advocacy activities.

Of course, the Section leadership is extremely interested in the response of members to these ideas and welcomes phone calls and emails with additional ideas or suggestions.

2007 NALJF Fellowship

By Edward J. Schoenbaum****

The National Administrative Law Judge Foundation, the public interest arm of the National Association of Administrative Law Judiciary, www.naalj.org, is requesting applications for the 2007 Fellowship. The Fellowship was endowed to encourage research and scholarship for improving administrative justice.

The topic for the 2007 Fellowship is "Administrative Due Process and Enemy Combatants."

The Fellowship will offer the successful candidate the opportunity to analyze a range of issues concerning the requirements of due process of law and the adjudication of claims related to enemy combatants. Candidates may address issues related to whether military commissions should operate under Due Process or APA type procedures, or how the *Matthew vs. Eldridge* interest analysis and administrative due process principles apply to adjudication of issues related to enemy combatants that are U.S. citizens or detainees held under the authority of the Supreme Court's *Hamden vs. Rumsfeld* decision. Alternatively, the candidate may analyze the current federal military commission statute enacted into law in 2006.

The Fellow will prepare an original article for publication in the Journal of the National Association of Administrative Law Judges, and will deliver a fifty-minute oral presentation at the

**** Administrative Law Judge, Illinois Department of Employment Security; Co-Chair State Administrative Law Committee; and Contributing Editor.

continued on page 28

News from the States

California Emergency Rules

By Michael Asimow*

Emergency rules create tension between two good policies. Often an agency must act immediately to deal with a true emergency; there is no time for leisurely notice and public comment. Yet public participation produces better rules. Under federal law, the dilemma is usually resolved through what are called “interim final” rules, meaning the agency adopts the rule and requests post-adoption public comments (in other words, it shoots first and asks questions later). The agency then considers those comments and re-adopts the rule as a final rule. Needless to say, post-adoption comments are not as effective as the normal pre-adoption comments, but they are a lot better than nothing. Of course, a court can still determine that there was no true emergency and thus the rule never qualified under the “good cause” exception of §553(b)(B) in the first place.

California law allows the adoption of emergency rules, but the agency’s declaration of emergency is reviewed by the

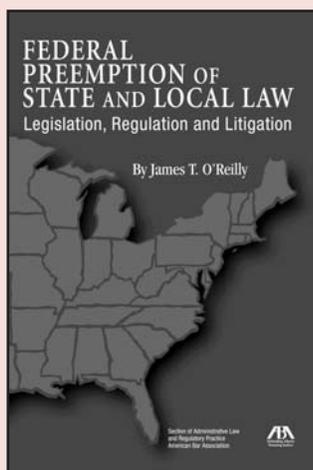
Office of Administrative Law (OAL), an executive branch agency that reviews all rules. In addition, the agency must provide notice and comment procedure on the rule after it is adopted. Under prior law, the notice and comment period had to be completed within 120 days after the rule was adopted (but OAL could grant unlimited extensions of the 120-day period).

An amendment that goes into effect in 2007 modifies this procedure. An agency must provide 5 working days advance notice of an emergency rule and OAL must wait an additional 5 days before taking action on the emergency rule to allow public comment. These two 5-day periods can be dispensed with if “the emergency situation clearly poses such an immediate serious harm that delaying action to allow public comment would be inconsistent with the public interest.” The agency has 180 days after adopting an emergency rule to complete notice and comment procedure; OAL can grant only two 90-day extensions of this period, so the agency must wrap up all procedural steps within one year of adopting an emergency rule. Thus the amendments enhance the public’s ability to comment on emergency rules before they are adopted, though commenters will have to be nimble to furnish input during the two 5-day comment periods. ○

* Professor of Law Emeritus, UCLA Law School; Section Chair-Elect; and Advisory Board Chair of the News.

From the ABA Section of Administrative Law and Regulatory Practice Federal Preemption of State and Local Law: Legislation, Regulation and Litigation

By James T. O’Reilly



Federal Preemption of State and Local Law addresses state-federal conflicts in the context of statutory preemption and “implied preemption” of state laws, state rules and state civil litigation. This comprehensive guide includes the latest Supreme Court decisions on administrative and products liability applications of the Constitution’s Supremacy Clause and the Tenth Amendment. Federal agencies, Congress and federal courts interact with state laws constantly. The case law of federal preemption has mushroomed in recent years, and the Supreme Court now deals with several preemption controversies each Term. This book will define and explain the types of preemption, the contexts, the statutes and the “applied” categories in which states and federal powers come into conflict. Order your copy today.

\$64.95 Administrative Law and Regulatory Practice section member price

\$74.95 Regular price

Product code: 5010047, ©2006, 6 x 9, 235 pages, paperback



For more information, or to order, visit our website www.ababooks.org or call (800) 285-2221.



The Third Annual Administrative Law and Regulatory Practice Institute

FEDERAL REGULATORY ENFORCEMENT ACTIONS

April 26–27, 2007 ★ Wyndham Washington Hotel ★ Washington, DC

Participants will examine emerging trends in federal regulatory enforcement from the agency perspective as well as the client perspective. The program begins with an overview, including “everything you need to know” in a lecture by Professor Alan Morrison of Stanford University. Participants will review a case study based on the Food and Drug Administration’s ban on ephedrine-alkaloid dietary supplements and the industry’s challenge to this rulemaking. The rulemaking and the ensuing litigation will be analyzed from the perspective of the agency, the industry and the public interest sector. Participants will discuss the impact of this enforcement measure in small group discussions. The program will close with a look at the new trend in global settlements, as currently being utilized by the EPA.

Everything you wanted to know about agency enforcement actions:

- ★ Administrative Agencies Are Just Like Legislatures and Courts— Except When They’re Not
- ★ Case Study: The Ephedra Ban and the Nutraceutical Litigation
- ★ Global Settlements – A New Twist on Agency Enforcement Actions

Small Group Discussions on:

- ★ The Agency Perspective
- ★ The Industry Perspective
- ★ The Public Interest Perspective

Keynotes by:

- ★ **Gregory Katsas**, Principal Deputy Associate Attorney General, US Department of Justice, Washington, DC
- ★ **Richard M. Cooper**, Partner, Williams and Connolly LLP, Washington, DC

Recent Articles of Interest *continued from page 24*

4. **Federalism in Securities Regulation: Rethinking the Balance**, 40 U. S. F. L. REV. 795, et. seq. (2006).
Articles by: i) Christopher M. Wood, *Federalism In Securities Regulation: A Brief Introduction and Reflection*, p. 795; ii) Joseph E. Stiglitz, *Federalism In Securities Regulation: An Economist’s Perspective*, p. 805; iii) James D. Cox, *The Role*

Of Empirical Evidence In Evaluating The Wisdom Of The Sarbanes-Oxley Act, p. 823; iv) Reza Dibadj, *From Incongruity To Cooperative Federalism*, p. 845; v) Donald C. Langevoort, *Federalism In Corporate/Securities Law: Reflections On Delaware, California, And State Regulation Of Insider Trading*, p. 879. ○

Section News & Events *continued from page 26*

annual meeting held in Washington, DC on October 17, 18, 19, and 20, 2007. Besides the \$1,000 cash stipend, the Fellow will receive air transportation, accommodations, and meals at the annual meeting and educational program. The final draft of the paper will be due January 1, 2008.

Applicants for the 2007 Fellowship should submit two copies of a detailed outline for the proposed article, an abstract or an introduction to the paper, with a writing sample, curriculum vitae, and a list of publications, by April 30, 2007. The

Fellowship Committee will review the submissions and select a Fellow by May 30, 2007. Applications and inquiries should be addressed to the Chair of the Fellowship Committee:

Christopher B. McNeil, Esq.
P.O. Box 595
Worthington, Ohio 43085-0595
(614) 571-6031
cmcneil@iwaynet.net. ○

OFFICERS, COUNCIL AND COMMITTEE CHAIRS

OFFICERS AND COUNCIL

Officers

Chair: Daniel E. Troy *
Chair-Elect: Michael R. Asimow*
Vice Chair: H. Russell Frisby, Jr.*
Secretary: James W. Conrad, Jr.*
Budget Officer: William S. Morrow*
Section Delegates: Judith Kaleta*
Thomas M. Susman*
Eleanor D. Kinney *

Last Retiring Chair: Eleanor D. Kinney *

* Executive Committee Member

Council

Member 2007: Bernard W. Bell
Kathleen E. Kunzer
Ronald L. Smith
Wendy E. Wagner
Member 2008: Michael Herz
Richard G. Stoll
Steve Vieux
Ann Marshall Young
Member 2009: Lisl J. Dunlop
Kenneth G. Hurwitz
William S. Jordan
Richard W. Parker

Ex-Officio

State Administrative Law: Paul G. Afonso
Executive Branch: Daniel Meron
Judiciary: A. Raymond Randolph
Legislative Branch: Consuela Washington
Adm. Judiciary: Lois F. Oakley

Liaisons

ABA Board of Governors: Mark Agrast
Young Lawyers Div.: Nicole Bernabo
Law Student Division: Phyra McCandless

ADMINISTRATIVE PROCESS COMMITTEES

Adjudication

Co-Chairs: James F. Flanagan
Ann Marshall Young

Constitutional Law and Separation of Powers

Co-Chairs: Bernard Bell
Yvette M. Barksdale

Corporate Counsel

Chair: Richard J. Wolf

Dispute Resolution

Chair: Charles E. Pou, Jr.

E-Rulemaking

Co-Chairs: Richard W. Parker
Peter L. Strauss

Government Information and Right to Privacy

Chair: James T. O'Reilly

Judicial Review

Chair: William S. Jordan, III

Legislative Process and Lobbying

Chair: William V. Luneburg

Ratemaking

Chair: Steven A. Augustino

Regulatory Policy

Chair: Sidney A. Shapiro

Rulemaking

Chair: Paul R. Noe

State Administrative Law

Co-Chairs: H. Lane Kneeder III
Edward J. Schoenbaum

GOVERNMENT FUNCTIONS COMMITTEES

Agriculture

Chair: Nancy S. Bryson

Antitrust and Trade Regulation

Chair: Chong S. Park

Banking and Financial Services

Chair: Charlotte M. Bahin

Benefits

Co-Chairs: Rudolph N. Patterson
Jodi B. Levine

Beverage Alcohol Practice

Co-Chairs: Richard M. Blau
Cary S. Wiggins

Communications

Co-Chairs: Scott D. Delacourt
Michael Sloan

Consumer Products Regulation

Co-Chairs: David H. Baker
Peter Lee Winik

Criminal Process

Co-Chairs: David Frulla
Jonathan J. Rusch

Defense and National Security

Co-Chairs: Thomas E. Crocker, Jr.
Lynne Zusman

Education

Chair: Nicole Bernabo

Elections

Co-Chairs: Trevor Potter
Sabine Romero

Ethics and Professional Responsibility

Chair: Myles Eastwood

Energy

Co-Chairs: Kenneth G. Hurwitz
Patrick J. McCormick, III

Environmental and Natural Resources Regulation

Co-Chairs: Timothy K. Webster
Robin K. Craig

Food and Drug

Chair: Coleen Klasmeier

Government Personnel

Chair: Joel P. Bennett

Health and Human Service

Chair: Christine Meis McAuliffe

Homeland Security

Co-Chairs: Lynne K. Zusman
Joe D. Whitley

Housing and Urban Development

Chair: Otto J. Hetzel

Immigration and Naturalization

Chair: Maria Pabon Lopez

Insurance

Chair: Janet E. Belkin

Intellectual Property

Chair: Arti K. Rai

International Law

Co-Chairs: Charles H. Koch
Kathleen E. Kunzer

International Trade & Customs

Chair: Leslie Alan Glick

Labor and Employment

Co-Chairs: Marc A. Antonetti
Robert J. Hickey

Ombuds

Chair: Nina E. Olson

Postal Matters

Chair: Robert J. Brinkmann

Public Contracts and Procurement

Chair: Howard J. Stanislawski

Securities, Commodities and Exchanges

Co-Chairs: James P. Gerkins
Susan Ellen Wolf

Transportation

Co-Chairs: Thomas Newton Bolling
Linda Lasley

Treasury, Revenue and Tax

Chair: Thomas H. Yancey

Veterans Affairs

Co-Chairs: Ronald Scholz
Ronald Smith
Barton F. Stichman

SECTION ACTIVITIES COMMITTEES

European Union Project

Chief Reporter: George Bermann
Asst Chief Reporters: Charles Koch
Jim O'Reilly
Fundraising Chair: Eleanor Kinney
Project Chair: Neil Eisner

Fellows

Chair: Paul Verkuil

Membership and Outreach

Chair: Renee Landers

Nominations

Chair: Randolph J. May

Pro Bono

Chair: Christine Monte

Professional Education

Co-Chairs: Susan Beth Farmer
John Hardin Young

Publications

Chair: Anna W. Shavers

Administrative and Regulatory Law News

Editor-in-Chief: William S. Morrow, Jr.

Administrative Law Review

Faculty Advisor: Andrew Popper
Editor-in-Chief: Christopher Chandler
Managing Editor: Jonathan Roberts

Developments in Administrative Law & Regulatory Practice

Editor: Jeffrey S. Lubbers

Seasonal Meetings

Fall Conference: Michael Herz
Steve Vieux
Midyear Meeting: Susan E. Johnson-Velez
Erin McCormick Larrinaga
William L. Hyde
Spring Meeting: Sabine Romero
Annual Meeting: Katherine M. Basile

Sponsorship

Subcommittee on Outstanding Government Service

Co-Chairs: Jodie Bernstein
Fred Emery
Cynthia Farina

Subcommittee on Scholarship

Co-Chairs: Richard W. Parker
Paul G. Afonso
Eleanor D. Kinney
Kenneth G. Hurwitz

Young Lawyers and Law Student Outreach

Co-Chairs: Christine Monte
Phyra McCandless
Nicole Bernabo

AD-HOC COMMITTEES

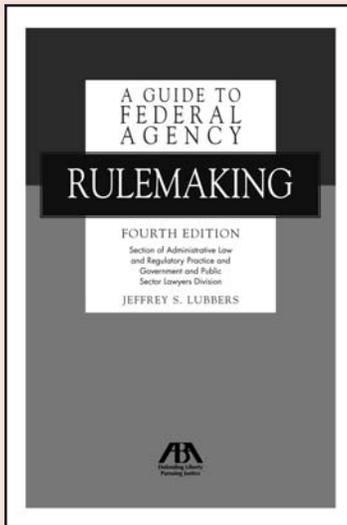
Review of Recruitment of ALJ's by OPM

Chair: John T. Miller

Review of Federal Preemption

Chair: William Funk

From the ABA Section of Administrative Law and Regulatory Practice
and the ABA Government and Public Sector Lawyers Division
A Guide to Federal Agency Rulemaking, Fourth Edition



By Jeffrey S. Lubbers

This fourth edition brings the essential *Guide to Federal Agency Rulemaking*, formerly published by the Administrative Conference of the United States (ACUS), completely up to date. A concise but thorough resource, the *Guide* provides a time-saving reference for the latest case law, and the most recent legislation affecting rulemaking. This manual provides agency rulemakers, participants in rulemaking and judicial review, and private practitioners with valuable insights into how federal rules are made, with an integrated view of the procedural requirements.

The new edition of *A Guide to Federal Agency Rulemaking*, written by Jeffrey S. Lubbers, former ACUS Research Director, retains the basic format of the previous editions while building upon the strong foundation established by ACUS in the previous editions. This fourth edition of *The Guide*, contains an index, and is organized into five parts:

- Part I is an overview of federal agency rulemaking and describes the major institutional “players” and historical development of rulemaking.
- Part II describes the statutory structure of rulemaking, including the relevant sections of the Administrative Procedure Act (APA).
- Part III contains a step-by-step description of the informal rulemaking process, from the preliminary considerations to the final rule, including a discussion of e-rulemaking.
- Part IV discusses judicial review of rulemaking with an expanded decision of the *Chevron* caselaw.
- Part V Appendices include key rulemaking documents.

This is an indispensable guide for anyone developing or drafting federal agency rules. Order your copy today.



\$64.95 Administrative Law
and Regulatory Practice
section member price

\$64.95 Government and Public
Sector Lawyers Division
member price

\$94.95 Regular price

Product code: 5010046, ©2006,
6 x 9, 723 pages, paperback



For more information, or to order, visit our website www.ababooks.org or call (800) 285-2221.

ADMINISTRATIVE & REGULATORY LAW NEWS

Volume 32, Number 3, Spring 2007

Published by the Section of
Administrative Law and Regulatory Practice
American Bar Association
740 15th Street, NW
Washington, DC 20005



Nonprofit Org.
U.S. Postage
PAID
Hagerstown MD
Permit No. 93