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ADMINISTRATIVE LAW MEETS HEALTH LAW: INEXTRICABLE PAIRING OR MARRIAGE OF CONVENIENCE?

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Thank you. It's an honor to be here. Eric asked me to speak with you about the Administration's health-care priorities and how they intersect with administrative law. It is, of course, odd to speak about administrative law as "meeting" health law, at least when you look at health law as I must, from the Government's perspective. Administrative law is our life's blood. We can't *do* anything without considering administrative law, from a press release, to a guidance, to a rule. For administrative law consists, at least in my mind, to a great extent of the questions "Do we have the substantive constitutional, statutory, or regulatory authority to do what we are doing?" and "Are we following the statutorily mandated procedures to do what we are doing?"

Today, I'd like to give you my personal perspective on the recent movement of the courts in the field of administrative law and how it impacts the work of an agency's general counsel. I'd also like to give you some background on the recently enacted Medicare Modernization Act and discuss some of the important administrative law modifications contained therein.[1]

I. THE RISE OF TEXTUALISM IN ADMINISTRATIVE LAW

From an agency perspective, the key development in administrative law over the last few decades has been the rise of textualism in statutory interpretation. Courts today tend to approach statutes by assessing the plain meaning of the text. In so doing, they refer to traditional canons and tools of statutory construction. In cases of ambiguity, some courts will resort to legislative history. They tend not to rely as much on the purpose of the statute as they once did. It is no longer sufficient for an agency to justify its action by declaring an intention to protect the public health and noting that the statute does not explicitly preclude a particular interpretation. As the Supreme Court said in *FDA v. Brown & Williamson Tobacco Corp.*, "[r]egardless of how

* General Counsel, U.S. Department of Health and Human Services. Keynote Address delivered at the 16th Annual Health Law Symposium of the Center for Health Law Studies and the Saint Louis University Law Journal on March 26, 2004.

1. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 177 Stat. 2066 [hereinafter Medicare Modernization Act].

serious the problem an administrative agency seeks to address, however, it may not exercise its authority in a manner that is inconsistent with the administrative structure that Congress enacted into law."[2]

And although the courts continue to speak in terms of deference to an agency's interpretation of the statutes which are entrusted to it to interpret, implement, and administer, agency action today is subject to closer scrutiny by the courts. This is illustrated by *United States v. Mead Corp.*,[3] where the Supreme Court held that certain agency actions were not entitled to *Chevron* deference[4] but only to *Skidmore* deference[5]—that is, deference in proportion to its power to persuade.

Finally, the courts—and the Office of Management and Budget—are closely scrutinizing, and with increasing skepticism, agency action accomplished not through notice-and-comment rulemaking but through guidance documents. There are at least two recent D.C. Circuit cases that invalidated guidance documents because the documents were really legislative rules that should have been promulgated through notice-and-comment rulemaking. These are *Appalachian Power Company v. EPA*[6] and *General Electric v. EPA*.[7]

In *Appalachian Power*, the court concluded that the EPA guidance at issue imposed obligations on State regulators and the regulated community that could not be traced to the Clean Air Act or EPA's implementing regulations.[8] It so held even though the guidance contained a "boilerplate" disclaimer at the end of the document that "[t]he policies set forth in this paper are intended solely as guidance, do not represent final Agency action, and cannot be relied upon to create any rights enforceable by any party."[9] The Court found that the document clearly created obligations.[10]

In *General Electric v. EPA*, the court concluded that the relevant EPA guidance document was a legislative rule because, as a practical matter, it bound applicants for approval of PCB clean-up plans to consider certain health risks by certain methods and the EPA to accept applications meeting certain criteria.[11] The court noted that its cases "make clear that an agency pronouncement will be considered binding as a practical matter if it either appears on its face to be binding, . . . or is applied by the agency in a way that

2. FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 125 (2000).
3. 533 U.S. 218, 221 (2001).
4. Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 865 (1984).
5. Skidmore v. Swift & Co., 323 U.S. 134, 140 (1999).
6. 208 F.3d 1015 (D.C. Cir. 2000).
7. 290 F.3d 377 (D.C. Cir. 2002).
8. *Appalachian Power Co.*, 208 F.3d at 1028.
9. *Id.* at 1023.
10. *Id.*
11. *General Electric*, 290 F.3d at 384.

indicates that it is binding."[12] The "mandatory language of a document alone can be sufficient to render it binding."[13]

The courts are not the only ones scrutinizing agencies' use of guidance. OMB is also taking a hard look at agency guidance. OMB has an obligation, under the Regulatory Right-to-Know Act, to promote recommendations for reforming the regulatory process and agency rules, as well as general duties to manage the efficiency and integrity of the regulatory process.[14] In OMB's 2002 Draft Report to Congress on the Costs and Benefits of Federal Regulations,[15] OMB discussed its "Review of Problematic Agency Guidance." It solicited public comment on problematic agency guidance, including those that "alter rights or impose obligations and costs not fairly discernible from the underlying statute or legislative rule that the document purports to interpret or implement."[16]

As agency counsel, I and my lawyers have taken these developments in administrative law very much to heart in how we advise our clients. Clients always want to do things quickly, especially when you are dealing with the public health and welfare, as we are in just about everything we do. But we try to convince our clients that it will serve their interests by doing things the right way. Often, this means using notice-and-comment rulemaking, which can be a long and arduous process. Many times our clients respond that they have in the past done the same thing through so-called "subregulatory documents," such as guidance and policy statements. But we ask them: Why give your opponents the chance to undo your good work by simply challenging a procedural flaw, without having to challenge your underlying substantive position? Don't give them a neutral and easy way to stop you in your tracks and embarrass you. In addition, learn from *Mead* that if you go through the rigors of notice-and-comment rulemaking, you will get deference to ambiguous terms.[17] And what you establish by rulemaking is much harder for your successors to undo.

We are constantly reminding our clients about the lessons of *Appalachian Power*[18] and *GE*[19]: Guidance must genuinely be guidance. We often cite the

12. *Id.* at 383.

13. *Id.*

14. Consolidated Appropriations Act of 2001, Pub L. No. 106-554, § 1(a)(3)[624], 114 Stat. 2763, 2763A-161 (codified at 31 U.S.C. §1105 (2003) note). The Regulatory Right-to-Know Act was implemented through the OMB Circular. *See* OFFICE OF MANAGEMENT AND BUDGET, THE EXECUTIVE OFFICE OF THE PRESIDENT, OMB CIRCULAR A-4 (Sept. 17, 2003).

15. 67 Fed. Reg. 15014 (March 28, 2002).

16. *Id.* at 15035.

17. *Mead*, 533 U.S. at 239 (Scalia, J., dissenting).

18. 208 F.3d at 1015.

19. 290 F.3d at 377.

example of the FDA's good guidance practices,[20] in which every guidance must state that the document "contains nonbinding recommendations" and that "[i]t does not create or confer any rights for or on any person and does not operate to bind FDA or the public."[21] Moreover, the guidance notes that "an alternative approach [can be used] if the approach satisfies the requirements of the applicable statutes and regulations."[22] And these can't be hollow words; they must actually be how the agency implements and understands its guidance.

We also encourage our clients to consider the enlightening and democratic value of notice and comment. This applies even in the guidance context, as the FDA does under its good guidance practices. For all of our talent, we are not the sole repository of learning on the subjects that we regulate. We can learn from public comment, and we can often achieve desired policy outcomes in better ways based on what we have learned. I encourage this approach even when dealing with legal interpretation issues. If policy-makers wish to achieve a particular policy result but we are having difficulty reaching that result as a matter of legal interpretation, I often suggest that we lay the issue out for the public, explain our legal quandary, and ask for assistance as to how to "get there" if that is indeed possible. At the FDA, we even put out a notice very early on that asked for public comment on the implications of the courts' recent First Amendment jurisprudence on FDA's regulatory practices.

II. MODERNIZING MEDICARE AND ADMINISTRATIVE LAW

Given their size and complexity, the Medicare and Medicaid programs raise a whole host of administrative law issues. In our effort to increase access to care over the past three years, we have, through Medicare and Medicaid waivers and state plan amendments, allowed states to expand access to health coverage for more than 2.6 million people and to expand the range of benefits offered to 6.7 million other Americans.[23] Although our waiver and demonstration project authorities under Medicare and Medicaid vest us with great discretion, many of these waivers—which involve waiving otherwise applicable statutory restrictions—present very unique and challenging administrative law issues. A major issue is whether states may impose prior approval requirements for the receipt of drugs by Medicaid recipients from pharmaceutical companies who refuse to enter into supplemental agreements

20. FDA Administrative Practices and Procedures: Good Guidance Practices, 21 C.F.R. §§ 7, 10, 14, 19, 25, 101, 107, 110, 114, 170, 310, 312, 314, 316, 500, 514, 601, 803, 814, 860 (2000).

21. *Id.*

22. *Id.*

23. Tommy, G. Thompson, Address to the Blank Rome Health Leadership Forum (Feb. 17, 2004) (transcript available at http://www.hhs.gov/news/speech/2004/040217.html).

with states—beyond those already required under federal law for drugs sold to Medicaid beneficiaries—to provide rebates or discounts for non-Medicaid beneficiaries. CMS determined that states would first have to seek the Secretary's approval under a state plan amendment to their Medicaid program and demonstrate a nexus to the Medicaid program; in other words, they would have to show how this arrangement would benefit the Medicaid program.[24] This position was vindicated in 2003 by the Supreme Court in *Pharmaceutical Research & Manufacturers of America v. Walsh*.[25] We also approved two Michigan programs that obtained supplemental rebates related to certain targeted low-income, non-Medicaid beneficiary populations; however, PhRMA sued us.[26] The District Court upheld our determination that these programs benefited Medicaid program by preventing low-income individuals from becoming Medicaid beneficiaries.[27] It is now on appeal to the D.C. Circuit.[28]

The waiver programs, of course, pale in comparison to the recently passed modernization of Medicare. For me, this is the most exciting possible time to be working at HHS. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003,[29] or MMA as we call it, promises to completely transform this program and bring twenty-first century medicine to the forty-year-old Medicare program.

For the first time, Medicare will offer a comprehensive prescription drug benefit to seniors, what is now called Part D of Medicare, starting in 2006. Seniors will be able to save money almost immediately through Medicare-endorsed drug discount cards. Estimates are that these cards will provide savings of 10 to 25%. Low-income seniors will get $600 on this card in each of 2004 and 2005 for their drug purchases.[30] These seniors will pay 5 to 10% coinsurance on discounted drug purchases using this transitional assistance.

24. Pharm. Research and Mfrs. of Am. v. Walsh, 538 U.S. 644, 650 (2003).

25. *Id.*

26. Pharm. Research and Mfrs. of Am. v. Thompson, 259 F. Supp. 2d 39, 46–47 (D. D.C. 2003).

27. *Id.* at 85.

28. On April 2, 2004, the week following the author's presentation, the D.C. Circuit decided this appeal in favor of the government. *See* Pharm. Research and Mfrs. of Am.. v. Thompson, 362 F.3d 817 (D.C. Cir. 2004).

29. Medicare Modernization Act, Pub. L. No. 108-173, 117 Stat 2066 (2003).

30. *Medicare Drug Card: Delivering Savings for Participating Beneficiaries: Hearing on Medicare Prescription Drug Discount Program Before the Senate Fin. Comm.*, 108th Cong. (2004) (forthcoming) (statement of Mark McClellan, Administrator, Centers for Medicare & Medicaid Services, *available at* http://finance.senate.gov/sitepages/hearing060804.htm).

Just yesterday, the Secretary announced the approval of 31 national cards, 19 regional cards, and cards from 43 Medicare Advantage organizations.[31]

The drug card has something of a sordid administrative law history. Shortly before I took office, CMS attempted to create a Medicare-endorsement program for pharmacy-benefits managers with established discount cards. CMS attempted to set up this program by a guidance document, which contained endorsement criteria and required that the endorsed cards participate in a consortium to share certain beneficiary information.[32] In a preliminary injunction order, the District Court in D.C. held that this initiative most likely created rights and obligations on private parties and, therefore, should have been subject to notice-and-comment rulemaking. It also found—on a preliminary basis—that CMS lacked the statutory authority to create an endorsement program. In response, CMS refined its program and put it out for notice-and-comment rulemaking. In that rulemaking, we provided an extensive discussion of CMS's comprehensive beneficiary education and assistance program authorities; of the requirements that formed the basis for this program; and of the program's purposes to bring drug discounts to beneficiaries on uncovered drugs, to enable them to avoid the need for more expensive Medicare medical care, and to inform them of their options.[33] In doing so, it was our position that we had followed *Mead*,[34] that greater deference is due to an agency's statutory interpretations when it has engaged in notice-and-comment rulemaking, and that we should win because of deference under *Chevron* step two.[35] The court again disagreed. In a ruling delivered from the bench, the court ruled against us under *Chevron* step one. We noticed an appeal, which then was mooted out by Congress's enactment of the MMA.

Speaking of which: In 2006, the comprehensive prescription drug benefit under the MMA will be available to seniors for about $35 a month.[36] Seniors will have a $250 deductible, and then Medicare will pay 75% of the costs between $250 and $2,250.[37] Seniors will pay 100% of the drug costs above total drug spending of $2,250 until they reach total drug spending of $5,100, of which $3,600 must be out-of-pocket spending.[38] After they have reached that

31. News Release, U.S. Dep't of Health & Human Servs., HHS Gives Seal of Approval to Medicare Drug Discount Cards (Mar. 25, 2004), *available at* http://www.hhs.gov/news/press/2004pres/20040325.html.

32. Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget, 66 Fed. Reg. 37,564, 37, 566 (July 18, 2001).

33. Medicare Program; Medicare-Endorsed Prescription Drug Card Assistance Initiative, 67 Fed. Reg. 10,262 (Mar. 6, 2002) (codified at 42 C.F.R. pt. 403).

34. United States v. Mead Corp., 533 U.S. 218 (2001).

35. *Id.* at 226–27.

36. Medicare Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066, 2072.

37. *Id.* at 2077.

38. *Id.*

limit, beneficiaries will pay the greater of 5% or $2 per generic drug and $5 for branded drugs.[39]

There's reduced cost sharing for low-income seniors. It's been estimated that the average senior currently without drug coverage will save about 50% on their drug spending, and low-income seniors will save even more.[40] Unlike traditional fee-for-service Medicare, this new benefit will be provided through private insurance companies and pharmacy-benefit managers, not a new government bureaucracy.

Similarly, there will be a larger role for private health delivery systems—meaning PPOs and managed care companies—in delivering health-care choices to Medicare beneficiaries through the newly renamed Medicare Advantage program. Beneficiaries will now be able to choose regional PPOs and enhanced HMOs. These plans will have the flexibility to offer additional benefits and customized beneficiary cost sharing.

MMA is also offering important new preventive services. In 2005, seniors will be able to get diabetes and heart disease screenings, and new beneficiaries will receive a "Welcome to Medicare Physical" that includes screenings and referrals to disease management programs.[41] In addition, MMA created tax incentives for individuals to purchase—and the marketplace to provide—health savings accounts. These accounts enable Americans to save for future medical expenses, tax-free.

With this background in mind, I'd like to discuss several changes that MMA makes in the application of administrative law to the Medicare program. The APA was enacted in 1946 to establish, among other things, "a pattern designed to achieve relative uniformity in the administrative machinery of the Federal Government."[42] While these basic APA procedures have worked well, Congress has from time to time created agency-specific standards and procedures. The Social Security Act already contained several particular administrative law provisions, such as a requirement that generally a sixty-day comment period is required for notice-and-comment rulemaking.[43]

The MMA made several important changes. First, HHS and OMB are required to establish and publish a regular timeline for the publication of final regulations based on the previous publication of an NPRM or an interim final

39. *Id.*

40. News Release, U.S. Dep't of Health & Human Servs., HHS Proposes New Rules to Deliver Better Benefits and Savings on Drugs for Medicare Beneficiaries (July 26, 2004), *available at* http://www.hhs.gov/news/press/2004pres/20040706.html.

41. Medicare: Issue of the Day, Welcome to Medicare Physical (January 06, 2004), *available at* http://www.cms.hhs.gov/medicare reform/issueoftheday/01062004iotd.pdf.

42. OFFICE OF ADMINISTRATIVE LAW JUDGES, U.S. DEP'T OF LABOR, *Introduction* to ATTORNEY GENERAL'S MANUAL OF THE ADMINISTRATIVE PROCEDURE ACT (1947), *available at* http://www.oalj.dol.gov/public/apa/refrnc/agintro.htm (last visited Oct. 12, 2004).

43. 42 U.S.C. § 405 (2000).

regulation.[44] CMS has to publish a notice in the Federal Register if it is unable to make the timeline for a particular regulation, including an explanation of the variance from the timeline, and if it does not publish a notice of continuance for an interim final rule, the rule will not remain in effect.

Second, the timeline from publication of an NPRM or an interim final regulation cannot exceed three years—except under exceptional circumstances. This is, in fact, consistent with a departmental initiative to withdraw out-of-date NPRMs so that resources can be deployed more efficiently. For example, the FDA published an NPRM a year ago in which it proposed to withdraw 88 NPRMs, many of which had been issued decades ago but were still on the books.[45]

Third, the MMA codifies for Medicare current administrative law on logical outgrowth: If a provision in a final regulation is not the logical outgrowth of a previous NPRM or interim final regulation, the provision will be treated as a proposed regulation and shall not take effect until there is an opportunity for public comment on the provision and a final rule is then issued.[46]

Fourth, and perhaps most importantly, MMA also grants CMS the power under certain circumstances to engage in retroactive rulemaking.[47] Under the APA, rulemaking is generally prospective in nature—and, in 1988, the Supreme Court specifically held, 9 to 0, in *Bowen v. Georgetown University Hospital*—that the Secretary lacked the authority to issue retroactive rules under the Medicare Act.[48] MMA changes that somewhat. Substantive changes in regulations, manual instructions, interpretative rules, statements of policy, and guidelines of general applicability can be applied retroactively if the Secretary determines that (1) retroactive application is necessary to comply with statutory requirements or (2) the failure to apply the change retroactively would be contrary to the public interest.[49]

Finally, if a Medicare provider or supplier follows certain erroneous written guidance provided by the Department or a Medicare contractor acting within the scope of its authority, the provider or supplier may seek to avoid penalties or interest on some overpayments.[50] This provides relief that was not previously available under the Supreme Court's decision in *Heckler v. Community Health Services of Crawford County*.[51]

44. Medicare Modernization Act, Pub. L. No. 108-173, 177 Stat. 2066, 2375 (2003).

45. Withdrawl of Certain Proposed Rules and Other Proposed Actions; Notice of Intent, 68 Fed. Reg. 19,766 (proposed Apr. 22, 2003).

46. Medicare Modernization Act, 117 Stat. at 2375.

47. *Id.* at 2376.

48. 488 U.S. 204, 209 (1988).

49. Medicare Modernization Act, 117 Stat. at 2376.

50. *Id.*

51. 467 U.S. 51 (1984).

I hope this sense of an agency general counsel's perspective on administrative law has been somewhat helpful. These are exciting times to be in public service and historic times to be working with the panoply of public health and welfare issues that HHS faces every day. I very much appreciate the opportunity to meet with you today about some of those issues. Thank you.