COERCED PARTICIPATION IN CLINICAL TRIALS: CONSCRIPTING HUMAN RESEARCH SUBJECTS

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INTRODUCTION

Biomedical research in this country depends heavily on an army of volunteers—persons willing, for one reason or another, to serve as experimental subjects. The supply of participants has not, however, kept pace with the growing demand.[1] Private research sponsors have found

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1. *See* Nancy S. Sung et al., *Central Challenges Facing the National Clinical Research Enterprise*, 289 JAMA 1278, 1279–80 (2003); Naomi Aoki, *Lack of Human Test Subjects a Bitter Pill for Drug Makers*, BOSTON GLOBE, Oct. 11, 2000, at D4; Thomas Ginsberg, *Please Stop Calling Them Drug 'Trials*,' PHILA. INQUIRER, June 21, 2006, at C1; Linda Marsa, *Clinical Trials Are Suffering: Suspicious of Medical Research, Volunteers Spurn Tests of Possibly Lifesaving Advances*, L.A. TIMES, Dec. 2, 2002, at F1; Virginia A. Smith, *Medical Testing Suffers from a Lack of Volunteers*, PHILA. INQUIRER, Apr. 6, 2004, at A1.

clever ways of recruiting new volunteers,[2] including controversial efforts at outsourcing the burden.[3] Governmental sponsors of research generally have eschewed such market-oriented solutions,[4] instead finding creative ways of encouraging otherwise unwilling subjects to "volunteer" for service. This Article describes and critiques the latter approach, focusing on a method recently developed to enroll Medicare beneficiaries in clinical trials.

This Article also provides an opportunity to evaluate official pronouncements on bioethics. This issue became prominent during the previous administration, with sometimes scathing and largely justified criticism of the President's Commission on Bioethics (PCB),[5] but potentially more radical pronouncements came from lower-level officials within the U.S. Department of Health and Human Services (HHS), particularly at the National Institutes of Health (NIH). Rather than the more easily dismissed tracts about hot-button social issues produced by ideologues serving on the PCB, these remarks about more technical issues appeared in the form of scholarly publications by respected academics doing stints in public service. For the most part, their articles did not attract the media's attention, but this very lack of visibility—coupled with a surprising absence of any sustained response by academics unaffiliated with the federal government—makes their provocative arguments potentially more insidious; surely not on a par with the infamous torture memos produced at the Department of Justice,[6] though with far broader potential impact.

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2. *See* Trudo Lemmens & Paul B. Miller, *The Human Subjects Trade: Ethical and Legal Issues Surrounding Recruitment Incentives*, 31 J.L. MED. & ETHICS 398 (2003); Rachel Zimmerman, *Desperately Seeking Kids for Clinical Trials*, WALL ST. J., May 29, 2002, at D1.

3. *See* Marc Kaufman, *Clinical Trials of Drugs Fewer, Study Says*, WASH. POST, May 4, 2005, at A2; Saritha Rai, *Drug Companies Cut Costs with Foreign Clinical Trials*, N.Y. TIMES, Feb. 24, 2005, at C4.

4. For an exception, see Ariana Eunjung Cha, *AIDS Vaccine Testing Goes Overseas: U.S. Funds $120 Million Trial Despite Misgivings of Some Researchers*, WASH. POST, May 22, 2006, at A1.

5. *See* Lars Noah, *A Postmodernist Take on the Human Embryo Research Debate*, 36 CONN. L. REV. 1133, 1148–52 (2004); Rick Weiss, *Conservatives Draft a 'Bioethics Agenda' for President*, WASH. POST, Mar. 8, 2005, at A6.

6. *See* Ross L. Weiner, Note, *The Office of Legal Counsel and Torture: The Law as Both a Sword and Shield*, 77 GEO. WASH. L. REV. 524, 526, 536–49 (2009); Charlie Savage & Scott Shane, *Terror-War Fallout Lingers over Bush Lawyers*, N.Y. TIMES, Mar. 9, 2009, at A1. Not surprisingly, when persons with legal training move into policymaking roles, they construe constraints on government action more loosely. *See* Lars Noah, *Interpreting Agency Enabling Acts: Misplaced Metaphors in Administrative Law*, 41 WM. & MARY L. REV. 1463, 1465 (2000); Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901, 917–19, 922 (2008).

I. LEVERAGING OPPORTUNITIES FOR KNOWLEDGE ACQUISITION

This Part describes three different ways that federal agencies have encouraged participation in biomedical research. It starts with a controversial Medicare initiative, which conditioned coverage for certain novel interventions on an agreement by beneficiaries to enroll in clinical trials, and then it compares and contrasts approaches used by the Pentagon and the Food and Drug Administration (FDA). The Medicare policy represents a variant of a practice that I previously had characterized as agency "arm-twisting" and critiqued primarily on *ultra vires* grounds.[7] Part II of this Article instead objects to the Medicare policy on ethical grounds.

A. Seniors

In 1996, the Health Care Financing Administration (HCFA), now the Centers for Medicare and Medicaid Services (CMS), began a bold experiment, both literally and figuratively. It conditioned payment for a new medical procedure on agreements by both beneficiaries to enroll in a randomized controlled trial (RCT) and participating surgeons not to offer the procedure to anyone who had not enrolled.[8] One decade later, after a few similar decisions,[9] CMS formalized this approach by issuing a guidance

7. *See* Lars Noah, *Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority*, 1997 WIS. L. REV. 873, 874 (explaining that arm-twisting "refers to a threat by an agency to . . . withhold a benefit in hopes of encouraging 'voluntary' compliance with a request that the agency could not impose directly"); *id.* at 899 ("Federal regulators are hardly alone in using leverage to extract voluntary commitments or concessions from private parties that they could not impose directly."); *see also Novel Procedures in FCC License Transfer Proceedings: Hearing Before the Subcomm. on Commercial & Administrative Law of the H. Comm. on the Judiciary*, 106th Cong. 29 (2000) (statement of Professor Lars Noah, University of Florida College of Law). In that article, I had focused on regulated entities (primarily companies); agency arm-twisting of beneficiaries (primarily individuals) obviously could pose more serious concerns. *Cf.* Noah, *supra*, at 903–08, 918–23 (finding parallels in criminal plea bargaining).

8. *See* Jeffrey M. Drazen, Editorial, *Surgery for Emphysema—Not for Everyone*, 345 NEW ENG. J. MED. 1126, 1127 (2001) ("One key factor set this trial apart: Medicare would no longer pay for the operation if it was performed outside the trial. Thus, prospective patients who were also Medicare recipients had only two choices if they wanted lung-volume–reduction surgery: participate in the trial or pay for the operation themselves."); *id.* (applauding this "unique" and "creative solution").

9. *See* Gina Kolata, *Medicare Covering New Treatments, but with a Catch*, N.Y. TIMES, Nov. 5, 2004, at A1 (discussing studies ordered by the Centers for Medicare and Medicaid Services (CMS) studies into off-label uses of new cancer drugs and positron emission tomography (PET) scans to diagnose Alzheimer's disease as well as proposed patient registries for implanted defibrillators, carotid stenting, and bariatric surgery); *id.* (adding that "Medicare does not intend to force studies of everything it pays for"); Rick Weiss, *Medicare to Cover Cardiac Device: Plan Raises Issue of Line Between Care and Research*, WASH. POST, Jan. 20, 2005, at A1 (explaining that the decision to cover implantable cardioverter-defibrillators (ICDs) for beneficiaries with congestive heart failure so long as they enroll in a patient

for "coverage with evidence development" (CED).[10] The CMS guidance described two forms of CED: coverage with appropriateness determination (CAD) and coverage with study participation (CSP).[11]

The 1996 study that inaugurated the CSP approach had much to commend it. Lung-volume reduction surgery for emphysema patients had become popular in the early 1990s without having undergone any rigorous study.[12] Indeed, five years later, the investigators published early results demonstrating that those in the sickest subgroup who underwent the surgery experienced greater mortality.[13] Since then, CMS has used its CED policy on only a handful of occasions,[14] including a 2005 decision to

registry "represents the most aggressive effort yet to use the federal insurance plan for the elderly as a backdoor way to learn more about what works and what does not in medicine").

10. *See* CMS, NATIONAL COVERAGE DETERMINATIONS WITH DATA COLLECTION AS A CONDITION OF COVERAGE: COVERAGE WITH EVIDENCE DEVELOPMENT (July 12, 2006), http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=8.

11. *See id.* at pt. V. The final guidance differed in important respects from a draft version issued one year earlier, which had failed to differentiate between these two study approaches. *See* CMS, FACTORS CMS CONSIDERS IN MAKING A DETERMINATION OF COVERAGE WITH EVIDENCE DEVELOPMENT (Apr. 7, 2005), http://www.cms.hhs.gov/coverage/download/guidanceced.pdf; Sean R. Tunis & Steven D. Pearson, *Coverage Options for Promising Technologies: Medicare's 'Coverage with Evidence Development,'* 25 HEALTH AFF. 1218, 1225–26 (2006). At around the same time, CMS officials penned a brief defense of a coverage with evidence development (CED) requirement for defibrillators. *See* Mark B. McClellan & Sean R. Tunis, *Medicare Coverage of ICDs*, 352 NEW ENG. J. MED. 222, 223 (2005) (focusing on the advantages of patient registries). Other countries have adopted similar policies. *See* John Hutton et al., *Coverage with Evidence Development: An Examination of Conceptual and Policy Issues*, 23 INT'L J. TECH. ASSESSMENT IN HEALTH CARE 425, 426 (2007).

12. *See* Mark R. Tonelli et al., *Clinical Experimentation: Lessons from Lung Volume Reduction Surgery*, 110 CHEST 230, 230–32 (1996); Gina Kolata, *Questions Raised on Lung Operation*, N.Y. TIMES, Aug. 15, 2001, at A1; *see also* Lars Noah, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 387–88 (2002) ("RCTs discredit long-accepted medical treatments with disturbing regularity . . . ."); *id.* at 393–94 ("[P]hysicians may embrace new procedures and technologies prematurely, before much evidence exists to support their enthusiasm."); *id.* at 447 ("The FDA's premarket review mechanisms and other controls generate substantial information about drugs and medical devices. No similar regulatory regime exists with regard to surgical techniques and other types of therapeutic interventions . . . ."). Although not something likely to have relevance to Medicare beneficiaries, fertility treatments have followed a similar trajectory. *See* Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 617–18, 665 (2003).

13. *See* Nat'l Emphysema Treatment Trial Research Group, *Patients at High Risk of Death After Lung-Volume–Reduction Surgery*, 345 NEW ENG. J. MED. 1075, 1080–82 (2001). Ultimately, the trial showed modest benefits for other patient subgroups, and CMS agreed to reimburse the surgery for such patients. *See* Scott D. Ramsey & Sean D. Sullivan, *Evidence, Economics, and Emphysema: Medicare's Long Journey with Lung Volume Reduction Surgery*, 24 HEALTH AFF. 55, 59–61 (2005). Nonetheless, surprisingly few beneficiaries thereupon underwent the procedure. *See* Gina Kolata, *Medicare Says It Will Pay, but Patients Say 'No Thanks,'* N.Y. TIMES, Mar. 3, 2006, at C1.

14. *See* Peter J. Neumann et al., *Medicare's National Coverage Decisions for Technologies,*

condition coverage of off-label uses of expensive new cancer drugs on enrollment in one of several RCTs sponsored by the National Cancer Institute.[15]

Some of the subsequent CEDs seemed harder to understand than the emphysema trial, particularly because they demanded studies of technologies that already had undergone extensive testing as a prelude to scrutiny by the FDA.[16] The latest CSP involves genetic testing of patients receiving the anticoagulant warfarin (Coumadin®). In 2007, the FDA announced revisions in the labeling of this drug to alert physicians that genetic testing might help to identify those patients who risk serious bleeding reactions because they metabolize the drug more slowly than normal—or are more sensitive to its effects—and therefore should receive a lower dose.[17] Nonetheless, two years later CMS announced that it would not cover genetic testing unless Medicare beneficiaries agreed to enroll in a clinical trial.[18] Although the cost-effectiveness of routine screening remains unclear and deserves continued investigation,[19] genetic testing for warfarin

1999–2007, 27 HEALTH AFF. 1620, 1623 (2008) ("CMS used its CED policy in seven decisions through 2007 . . . . Five of the cases involved clinical trials, while two involved data registries."). Their two most recent listed illustrations required participation in RCTs for beneficiaries with less severe impairments as a condition of access to cochlear implants and home-use oxygen. *See id.* at 1627 exh.5 (adding that, in the case of cochlear implants, "[n]o proposals for trials emerged in response"); *see also id.* at n.a ("Several cases that we call CED predate these formal [2005 and 2006] guidances."); *id.* at 1628 (mentioning a "flurry" of more recent CED proposals).

15. *See* Tanisha Carino et al., *Medicare's Coverage of Colorectal Cancer Drugs: A Case Study in Evidence Development and Policy*, 25 HEALTH AFF. 1231, 1235 (2006); *see also id.* at 1237–38 (drawing parallels to the emphysema research, but adding that most other CEDs have involved patient registries). Private insurers have done likewise in some circumstances. *See* Gina Kolata & Kurt Eichenwald, *Group of Insurers to Pay for Experimental Cancer Therapy*, N.Y. TIMES, Dec. 16, 1999, at C1.

16. CMS does not simply defer to FDA approval decisions, even though both agencies reside within the same cabinet-level department. *See* Christopher D. Zalesky, *Considering Changes to CMS's National Coverage Decision Process: Applying Lessons Learned from FDA as a Regulator of Access to Healthcare Technology*, 57 FOOD & DRUG L.J. 73, 76 (2002).

17. *See* David Brown, *For the First Time, FDA Recommends Gene Testing*, WASH. POST, Aug. 17, 2007, at A10; Bernadette Tansey, *A Specific Test for What Ails You*, S.F. CHRON., Sept. 9, 2007, at E1; *see also* Int'l Warfarin Pharmacogenetics Consortium, *Estimation of the Warfarin Dose with Clinical and Pharmacogenetic Data*, 360 NEW ENG. J. MED. 753, 754, 759–60 (2009); Mollie Roth, *The Warfarin Revised Package Insert: Is the Information in the Label "Too Thin"?*, 9 HOUS. J. HEALTH L. & POL'Y 279 (2008). *See generally* Lars Noah, *The Coming Pharmacogenomics Revolution: Tailoring Drugs to Fit Patients' Genetic Profiles*, 43 JURIMETRICS J. 1 (2002).

18. *See* Andrew Pollack, *Gene Test for Dosage of Warfarin Is Rebuffed*, N.Y. TIMES, May 5, 2009, at B3 (describing the CMS announcement as a proposal with a one month public comment period). "As many as one million or more Medicare patients a year start therapy with the drug, which is used to prevent life-threatening blood clots." *Id.*

19. *See id.* ("Some studies have shown that using the genetic test might allow the proper

sensitivity would appear to have no downside from the perspective of particular patients or their physicians.

HCFA previously had tried a different approach to encouraging study participation by the elderly. In 2000, the agency extended Medicare coverage for ancillary costs incurred by beneficiaries who chose to enroll in clinical trials,[20] but this policy expressly excluded any payment for the investigational item or service.[21] In contrast, with its CED policy CMS has offered to cover the cost of an item or service, but only when beneficiaries agree to facilitate further investigation. Some critics have argued that CMS has used the CED process for simple delay or implicit rationing of expensive new medical interventions.[22] To be sure, other federal agencies have imposed study requirements as a way of postponing difficult regulatory judgments about continued product marketing.[23] This Article

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dose to be achieved more quickly. But Medicare said there was little evidence that doing so translated into a lower risk of blood clots or hemorrhages."); *id.* ("[K]nowing which variants of the two genes a patient has does not automatically tell the doctor what dose to give. That depends on other factors as well. Moreover, use of the genetic tests does not eliminate the need to periodically test the patient's blood-clotting propensity."); *see also* Mark H. Eckman et al., *Cost-Effectiveness of Using Pharmacogenetic Information in Warfarin Dosing for Patients with Nonvalvular Atrial Fibrillation*, 150 ANNALS INTERNAL MED. 73, 80–81 (2009); *cf.* Marie McCullough, *Hopes Rising on Finding a Better Blood Thinner*, PHILA. INQUIRER, Oct. 20, 2009, at A1 (describing new and safer substitutes).

20. *See* David Brown, *Medicare to Pay for Experimental Treatments: Clinton Aims to Bring More Seniors into Clinical Trials*, WASH. POST, June 8, 2000, at A9; *see also* Kirk Dobbins & Kay Scanlan, *Medicare's Revised Clinical Trial Policy and Clinical Trial-Related Provisions of FDAAA: What Is a Sponsor to Do?*, 62 FOOD & DRUG L.J. 695, 696–704 (2007) (discussing subsequent developments). This represented an attempt to respond to reports that RCTs included too few elderly subjects. *See, e.g.*, Laura F. Hutchins et al., *Underrepresentation of Patients 65 Years of Age or Older in Cancer-Treatment Trials*, 341 NEW ENG. J. MED. 2061, 2064–66 (1999); *see also* INST. OF MED., EXTENDING MEDICARE REIMBURSEMENT IN CLINICAL TRIALS (2000).

21. *See* Notice of Public Meeting on Medicare Coverage of Clinical Trials, 65 Fed. Reg. 60,442, 60,443 (Oct. 11, 2000).

22. *See* Sandra J. Carnahan, *Medicare's Coverage with Study Participation Policy: Clinical Trials or Tribulations?*, 7 YALE J. HEALTH POL'Y L. & ETHICS 229, 256, 258, 267–68, 272 (2007); Peter W. Groeneveld, Letter to the Editor, *Medicare Requirement for Research Participation*, 296 JAMA 2923 (2006); Carol Gentry, *Why Medicare Covers a New Lung Surgery for Just a Few Patients*, WALL ST. J., June 29, 1998, at A1. Although CMS may limit its reimbursement levels, the agency cannot consider expense when deciding whether or not to cover a medical intervention. *See* Carnahan, *supra*, at 257; *infra* note 82; *see also* Alex Berenson, *Medicare Cuts Payout on 2 Cancer Drugs*, N.Y. TIMES, Dec. 7, 2007, at C3; Andrew Pollack, *Stronger Warnings on 3 Drugs for Anemia*, N.Y. TIMES, Nov. 9, 2007, at C3; Jane Zhang, *Medicare Official Key to Spending*, WALL ST. J., Oct. 27, 2009, at A6. Thus, paying only for enrolled subjects and putting off a final coverage decision until completion of a study allows the agency to limit early access to expensive medical innovations and thereby ration care.

23. *See, e.g.*, Lars Noah & Richard A. Merrill, *Starting from Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329, 382–85 (1998) (discussing "interim" food additives); *see also* Lars Noah, *The Imperative to Warn: Disentangling the "Right to Know" from the "Need to Know" About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 397 (1994)

focuses, instead, on the serious ethical questions posed by the CSP policy, but first it contrasts that approach with other federal efforts to encourage individuals to participate in research.

B. Soldiers

The U.S. military has a checkered history when it comes to human experimentation. During the height of the Cold War, for example, the Department of Defense (DOD) sponsored experiments in which cancer patients and prisoners were exposed to total body radiation or plutonium in order to test the body's response, but the investigators made no effort to secure informed consent from the subjects.[24] Most military research efforts have, however, taken advantage of the large pool of active—and, for the most part, highly compliant—service members.[25]

In 1990, the FDA granted a request from the DOD for an exemption to informed consent requirements during the Gulf War in order to inoculate military personnel with unapproved treatments for biowarfare agents.[26]

(explaining comparable motivations behind risk labeling). Along similar lines, the FDA occasionally withdraws the license for a previously approved drug but allows continued use under the strictures of an investigational new drug (IND) exemption. *See, e.g.*, Forsham v. Califano, 442 F. Supp. 203, 205, 210 (D.D.C. 1977) (phenformin); Francesca Lunzer Kritz, *FDA to Weigh New Controls on Problematic Drugs: Lotronex Will Be First for Consideration by New Panel*, WASH. POST, Apr. 16, 2002, at F1 (Propulsid®); Andrew Pollack, *F.D.A. Restricts Access to Cancer Drug, Citing Ineffectiveness*, N.Y. TIMES, June 18, 2005, at C2 (reporting that patients who had benefitted from Iressa® could continue to use it and that the sponsor could continue enrolling subjects in clinical trials).

24. *See In re* Cincinnati Radiation Litig., 874 F. Supp. 796, 800–05 (S.D. Ohio 1995); *see also* CIA v. Sims, 471 U.S. 159, 162 & n.2 (1985) (LSD experiments); Barrett v. United States, 660 F. Supp. 1291, 1299 (S.D.N.Y. 1987) (Army testing of mescaline-derivatives as potential chemical warfare agents on mental hospital patients without their consent). Civilian agencies and private institutions participated in the human radiation experiments as well. *See* Stadt v. Univ. of Rochester, 921 F. Supp. 1023, 1025 (W.D.N.Y. 1996); Advisory Comm. on Human Radiation Experiments, *Research Ethics and the Medical Profession*, 276 JAMA 403 (1996); Nestor M. Davidson, Note, *Constitutional Mass Torts: Sovereign Immunity and the Human Radiation Experiments*, 96 COLUM. L. REV. 1203, 1203–04, 1226–28, 1233–35 (1996); *see also* Begay v. United States, 768 F.2d 1059, 1060–62, 1064–66 (9th Cir. 1985) (prospective epidemiological study conducted by the U.S. Public Health Service on Navajo uranium miners). *See generally* JONATHAN D. MORENO, UNDUE RISK: SECRET STATE EXPERIMENTS ON HUMANS (2000).

25. *See, e.g.*, United States v. Stanley, 483 U.S. 669, 686–89 (1987) (Brennan, J., dissenting in part) (criticizing the Army's secret LSD experiments); Jaffee v. United States, 663 F.2d 1226, 1229 (3d Cir. 1981) (en banc) (nuclear fallout); Thom Shanker, *Reports Detail Tests of Troops for Exposures*, N.Y. TIMES, July 1, 2003, at A21.

26. *See* Informed Consent for Human Drugs and Biologics; Determination That Informed Consent Is Not Feasible, 55 Fed. Reg. 52,814, 52,817 (Dec. 21, 1990) (codified as amended at 21 C.F.R. § 50.23(d) (2009)). Although some have argued that the DOD sought only to provide treatment for soldiers rather than engage in genuine research, the FDA's waiver clearly anticipated that study protocols would govern the use of the unapproved

Military officials feared that some soldiers would refuse, which then might create difficulties in the field in the event of exposure to biological and chemical weapons. Apart from doubts about the military's claim that this made it "not feasible" to secure informed consent, which represents the statutory standard for waiving the FDA's requirements,[27] Congress had imposed separate consent requirements on the DOD for "research involving a human being as an experimental subject."[28] The federal courts, however, rejected a challenge to the FDA's waiver of informed consent requirements.[29] Expressing evident displeasure with these rulings, Congress subsequently mandated that the DOD secure informed consent from military personnel before administering an investigational drug (whether or not done in connection with genuine experimentation), including an approved drug for an unapproved use, and it provided that only the President could waive this requirement.[30]

These issues returned after 2001, with concerns about bioterrorist attacks in the United States. Under a program begun in 1998 but not fully implemented until mid-2002 (shortly before the invasion of Iraq), the DOD inoculated service members and certain civilian contractor employees with anthrax vaccine adsorbed (AVA).[31] The FDA licensed the vaccine for the

products, that other human subject protections would remain in place, and that the DOD would collect data in pursuit of filing applications for marketing approval. *See id.* at 52,815–16.

27. *See* 21 U.S.C. § 355(i)(4) (2006).

28. Department of Defense Authorization Act of 1985, Pub. L. No. 98-525, § 1401(c), 98 Stat. 2492, 2615 (1984) (codified at 10 U.S.C. § 980 (2006)); *see also* Elliott J. Schuchardt, *Distinguishing Between Research and Medical Practice During Operation Desert Storm*, 49 FOOD & DRUG L.J. 271, 277–89 (1994) (concluding that the DOD had not conducted research in violation of this statute); Ruth K. Miller, Note, *Informed Consent in the Military: Fighting a Losing Battle Against the Anthrax Vaccine*, 28 AM. J.L. & MED. 325, 339–43 (2002) (defending the DOD's program).

29. *See* Doe v. Sullivan, 756 F. Supp. 12, 16 (D.D.C.) ("The fact that the DoD will collect information on the efficacy of the drugs does not transform the strategic decision to use the unapproved drugs in combat into research."), *aff'd*, 938 F.2d 1370, 1379–83 (D.C. Cir. 1991); *see also* George J. Annas, *Changing the Consent Rules for Desert Storm*, 326 NEW ENG. J. MED. 770, 772 (1992) (agreeing that the DOD was not engaging in research); Robyn Pforr Ryan, *Should Combat Troops Be Given the Option of Refusing Investigational Drug Treatment?*, 52 FOOD & DRUG L.J. 377, 393 (1997) (criticizing the waiver, noting that, although "DOD did not administer the treatment with the primary intent of generating new knowledge," the drugs were experimental in the sense that uncertainty remained about their safety and efficacy); Claire A. Milner, Comment, *Gulf War Guinea Pigs: Is Informed Consent Optional During War?*, 13 J. CONTEMP. HEALTH L. & POL'Y 199, 223–31 (1996).

30. *See* Pub. L. No. 105-85, § 766(a), 111 Stat. 1629, 1827 (1997) (codified as amended at 10 U.S.C. § 1107 (2006)); *see also* Exec. Order No. 13,139, 64 Fed. Reg. 54,175, 54,176 (Oct. 5, 1999) (announcing that the President would evaluate waiver requests using the criteria set forth in the FDA's regulation).

31. *See* Guy Gugliotta, *Pentagon to Resume Anthrax Vaccinations*, WASH. POST, June 29, 2002, at A3.

prevention of cutaneous anthrax, but it had expressed doubts about its efficacy against inhalation anthrax,[32] and, in 1996, the manufacturer submitted an investigational new drug (IND) application to undertake research that would support adding that indication to the labeling.[33] The military's Anthrax Vaccine Immunization Program (AVIP) did not, however, make any provision for securing informed consent before inoculating soldiers with AVA.[34]

A group of service members and civilian employees challenged the program, arguing that the use of a drug to protect against the risk of inhalation anthrax but licensed only to guard against cutaneous exposure was investigational and therefore required informed consent under statute unless waived by a presidential order.[35] After rejecting the government's nonjusticiability arguments,[36] and concluding that AVA remained "investigational" against inhalation anthrax,[37] a federal judge granted petitioners a preliminary injunction. The court found no merit in the DOD's claims of necessity,[38] and it concluded that, "[a]bsent an informed consent or presidential waiver, the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs."[39]

One week after the court's order (and eighteen years after issuing its proposal), the FDA published a final rule that found AVA safe and effective for protection against inhalation anthrax.[40] After invalidating this rule on procedural grounds, the district court issued a permanent injunction against implementation of the AVIP.[41] In response, the government invoked a newly enacted provision that authorized the use of unapproved drugs during a declared national emergency.[42] Just as the six-month

32. *See* Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, 50 Fed. Reg. 51,002 (Dec. 13, 1985).

33. *See* Randall D. Katz, Note, *Friendly Fire: The Mandatory Military Anthrax Vaccination Program*, 50 DUKE L.J. 1835, 1853–54, 1859 (2001).

34. *See* Doe v. Rumsfeld, 297 F. Supp. 2d 119, 125 (D.D.C. 2003).

35. *See id.* at 122–23.

36. *See id.* at 126–31.

37. *See id.* at 131–34.

38. *See id.* at 134.

39. *Id.* at 135.

40. *See* Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, 69 Fed. Reg. 255, 259 (Jan. 5, 2004).

41. *See* Doe v. Rumsfeld, 341 F. Supp. 2d 1, 19 (D.D.C. 2004); *cf.* Ammend v. BioPort, Inc., 322 F. Supp. 2d 848, 870–73 (W.D. Mich. 2004) (rejecting constitutional claims against entities that had supplied anthrax vaccine to DOD).

42. *See* Marc Kaufman, *Pentagon Boosts Plan for Anthrax Inoculations: Emergency Provisions Invoked to Revive Use*, WASH. POST, Feb. 2, 2005, at A3 (reporting that soldiers would have the right to refuse). When it authorized the use of unapproved medical products in the event of an emergency (and without distinguishing between civilians and military personnel),

authorization for emergency use of AVA expired, the FDA reissued its final order concluding that the vaccine was effective against inhalation anthrax,[43] which removed the drug from IND status and thereby avoided application of the consent requirements imposed by Congress.[44]

At some level, the Pentagon's tortuous efforts over the last couple of decades to avoid securing informed consent seem odd. After all, presumably it could discharge (dishonorably or otherwise) any service member who refused to consent, which would mean that only rarely would a soldier decline to participate.[45] Perhaps military officials realized that consent to research secured under such circumstances would not pass muster as genuinely voluntary.[46] Of course, once the FDA approves a medical product for a particular use, the special consent requirements governing experimentation become inapplicable, and the Pentagon then could force military personnel to get inoculated or face discharge in the event of refusal.[47]

Congress also had included an informed consent requirement. *See* Project BioShield Act of 2004, Pub. L. No. 108-276, § 4(a), 118 Stat. 853 (codified at 21 U.S.C. § 360bbb-3(e)(1)(A)(ii) (2006)).

43. *See* Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Anthrax Vaccine Adsorbed, 70 Fed. Reg. 75,180, 75,183 (Dec. 19, 2005).

44. *See* Doe v. Rumsfeld, 172 F. App'x 327, 328 (D.C. Cir. 2006) (per curiam) (rejecting the government's appeal as moot because the FDA's approval satisfied the district court's injunction).

45. *See* Neely Tucker, *Anthrax Vaccine Challenged: Two Suing Defense Department over Inoculation Policy*, WASH. POST, May 15, 2002, at A10 (reporting that approximately 500 service members had declined anthrax vaccinations and that some of those faced courts martial).

46. *See* Keri D. Brown, Comment, *An Ethical Obligation to Our Servicemembers: Meaningful Benefits for Informed Consent Violations*, 47 S. TEX. L. REV. 919, 935 (2006) (calling the "voluntariness" element arguably the biggest problem for the military and the reason they have procedures for informed consent waivers); *cf.* Scott Fontaine, *Blood Pressure Pill Slays Nightmares*, WASH. POST, Dec. 31, 2009, at A15 (reporting that military hospitals have recruited active service members and veterans to participate in genuine research of a promising off-label use of prazosin).

47. *See* George J. Annas, *Protecting Soldiers from Friendly Fire: The Consent Requirement for Using Investigational Drugs and Vaccines in Combat*, 24 AM. J.L. & MED. 245, 250, 257 & n.47 (1998); Katz, *supra* note 33, at 1848; *Pentagon Set to Vaccinate Troops, Assist in Flu Crisis*, WASH. POST, Sept. 30, 2009, at A6; *see also* Catherine L. Annas & George J. Annas, *Enhancing the Fighting Force: Medical Research on American Soldiers*, 25 J. CONTEMP. HEALTH L. & POL'Y 283, 291 (2009) ("'Questions of coercion and autonomy are particularly acute for military personnel . . . . Soldiers in the United States . . . *are legally required to take medications if ordered to for the sake of military performance*.'" (quoting Henry Greely et al., *Towards Responsible Use of Cognitive-Enhancing Drugs by the Healthy*, 456 NATURE 702, 703 (2008))); *cf. id.* at 300 (questioning this premise); *id.* at 296 n.58 (quoting a consent form that military pilots "are required to sign" before taking dextroamphetamine off-label to manage fatigue); *id.* at 308 ("The military rule should be that prescription medications should never be forced on soldiers, but should be taken only voluntarily, and only on the advice of a physician who cannot be ordered to prescribe it.").

C. Civilians

In contrast to CMS, which deals with beneficiaries and providers through reimbursement choices (and affects sellers only indirectly), and in contrast to DOD, which controls service members (and, in any event, generally does not engage in genuine medical research), the FDA exercises its authority over sellers of medical technologies (and affects patients and providers only indirectly). Thus, where CMS would find it difficult to obligate sellers to undertake further research as a condition of coverage (and certainly could not force beneficiaries to participate in such research),[48] the FDA may do so as a condition of approval. Even if undertaken by private industry at the behest of a regulatory agency, these research requirements may have the same potentially adverse impact on patients seeking access to new technologies.

The FDA requires that, before shipping an unapproved new drug to initiate human trials, sponsors file an IND application.[49] The results of these trials provide the basis for agency decisions when sponsors subsequently file an application for new drug approval (NDA).[50] Even if the FDA acts favorably on the NDA, this hardly closes the book on the safety and efficacy of a regulated product. The issuance of a product license does not magically transform an investigational medical technology into one that has matured fully and requires no additional scrutiny.[51]

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48. Actually, the CED policy indirectly creates pressure on sellers as well as beneficiaries. *See* Kolata, *supra* note 9, at A1 ("For the first time in its history, Medicare has systematically begun to make payments for new and expensive treatments and diagnostic tests conditional on agreement by companies or other groups to pay for studies on whether these new methods actually work on the Medicare patients who get them."); *id.* ("[CMS] is using the threat of refusing to pay unless patients are in a study as a cudgel to get companies or foundations or professional groups to pay for the research."); *id.* ("[W]ith Medicare the dominant payer for elderly Americans, who are most likely to need the treatments, its clout, when it insists on studies, is substantial.").

49. *See* 21 U.S.C. § 355(i) (2006); 21 C.F.R. pt. 312 (2009); *see also* David A. Kessler, *The Regulation of Investigational Drugs*, 320 NEW ENG. J. MED. 281, 281 (1989); Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1766–67, 1777–82 (1996). Similarly, sponsors of certain medical devices must apply for an investigational device exemption (IDE) before undertaking clinical trials. *See* 21 U.S.C. § 360j(g); 21 C.F.R. pt. 812; *see also* Martin v. Telectronics Pacing Sys., Inc., 105 F.3d 1090, 1095–96 (6th Cir. 1997).

50. *See* 21 U.S.C. § 355(b); 21 C.F.R. pt. 314.

51. *See* Annetine C. Gelijns et al., *Capturing the Unexpected Benefits of Medical Research*, 339 NEW ENG. J. MED. 693, 693 (1998) ("The end of the research-and-development process does not entail the elimination of all, or even most, of the uncertainties surrounding medical innovation."); Margaret Gilhooley, *When Drugs Are Safe for Some but Not Others: The FDA Experience and Alternatives for Products Liability*, 36 HOUS. L. REV. 927, 936 (1999) (recognizing that "the initial use of a drug is, in effect, a continuation of the testing" phase); Wayne A. Ray et al., *Evaluating Drugs After Their Approval for Clinical Use*, 329 NEW ENG. J. MED. 2029,

In particular, safety questions often arise after approval.[52] For that reason, researchers increasingly have taken advantage of databases maintained by health insurers, both public and private.[53] For instance, Medicare billing records may allow investigators to discern rates of complications associated with particular procedures.[54] Similarly, the FDA has discovered important drug side effects from retrospective reviews of Medicaid records,[55] and the agency has announced plans to make more regular use of such sources of information in the future.[56]

Patient registries provide a somewhat more structured mechanism for tracking outcomes. During the 1990s, the FDA (together with HCFA) used a registry to evaluate cardiac pacemakers.[57] The agency also has urged that

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2029–30 (1993).

52. *See* U.S. GEN. ACCOUNTING OFFICE, FDA DRUG REVIEW: POST APPROVAL RISKS 1976–85, at 3 (1990) (concluding that more than half of all drugs approved between 1976 and 1985 had serious risks that were discovered only after approval); Karen E. Lasser et al., *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 JAMA 2215, 2218–19 (2002); Robert J. Temple & Martin H. Himmel, Editorial, *Safety of Newly Approved Drugs: Implications for Prescribing*, 287 JAMA 2273, 2275 (2002); Naomi Aoki, *A Question of Speed and Safety*, BOSTON GLOBE, Nov. 28, 2001, at G1 (noting "the growing number of drugs that have been recalled in the past three years—nearly a dozen implicated in more than 1,000 deaths").

53. *See* Wayne A. Ray et al., *Adverse Drug Reactions and the Elderly*, HEALTH AFF., Fall 1990, at 114, 120; Ricardo Alonso-Zaldivar, *Medicare's Will May Be FDA's Way*, L.A. TIMES, June 5, 2005, at A1; David Brown, *Congress Seeks to Balance Drug Safety, Quick Approval*, WASH. POST, July 5, 2007, at A4.

54. *See, e.g.*, Steve Sternberg, *Higher Price for Defibrillator Implants*, USA TODAY, June 26, 2006, at 5D (reporting that such a review found higher-than-expected rates of complications and associated hospitalization costs associated with ICDs); *id.* ("[CMS] hopes to use a registry started in January 2005 to sharpen the focus on why so many complications are occurring and how to reduce their number. The registry now has records from 51,000 patients."); *see also* Stephen F. Jencks et al., *Quality of Medical Care Delivered to Medicare Beneficiaries: A Profile at State and National Levels*, 284 JAMA 1670, 1675–76 (2000).

55. *See, e.g.*, David Brown, *Blood-Pressure Drugs Linked to Birth Defects*, WASH. POST, June 8, 2006, at A12 (reporting that research funded by the FDA and using one state's Medicaid records discovered a significant increase in the risk of birth defects when pregnant women used ACE inhibitors during their first trimester).

56. *See* News Release, FDA, Health Organizations to Study Safety of Medications Taken During Pregnancy (Dec. 30, 2009), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm195934.htm; Rob Stein, *Program Aims for Drug, Device Safety*, WASH. POST, May 23, 2008, at A2; *see also* Medicare Program; Medicare Part D Data, 71 Fed. Reg. 61,445, 61,450–52 (proposed Oct. 18, 2006) (to be codified at 42 C.F.R. pt. 423); Natasha Singer, *Public Database Is Urged to Monitor Drug Safety*, N.Y. TIMES, Nov. 24, 2009, at B2.

57. *See* Cardiac Pacemaker Registry, 52 Fed. Reg. 27,756, 27,763–64 (July 23, 1987) (codified at 21 C.F.R. pt. 805 (1999)) (making Medicare reimbursement of physicians, hospitals, and other providers contingent on providing information about the implantation or removal of these devices), *revoked*, 64 Fed. Reg. 66,105 (Nov. 24, 1999). Newer agency initiatives have focused on the establishment of "sentinel" (early warning) systems. *See* Ross Kerber, *FDA Halts Expansion of Network to Monitor Medical Device Safety*, BOSTON GLOBE, July

patients taking suspected teratogens enroll in pregnancy registries, as it did in the case of Accutane® (isotretinoin).[58] Congress recently granted the FDA explicit authority to impose these and other sorts of postapproval study requirements on manufacturers of new drugs.[59]

These programs vaguely resemble the product registration cards that accompany many consumer goods and that most purchasers discard.[60] If obligatory, in the sense that patients must register before receiving a particular drug or device, then such tracking mechanisms seem a bit more intrusive.[61] Even so, patients would face little additional burden and presumably later would remain free to decline to respond to any follow-up requests for information unless they continue using and do not want to lose access to the product at issue. Furthermore, though the FDA has the power to demand that manufacturers undertake rigorous research after approval (so-called Phase IV trials),[62] it generally has no way to encourage

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14, 2005, at D1.

58. The manufacturer had included an enrollment form for patients to send to the Slone Epidemiology Unit at Boston University's School of Public Health that facilitated the tracking of patient compliance and adverse outcomes. *See* Allen A. Mitchell et al., *A Pregnancy-Prevention Program in Women of Childbearing Age Receiving Isotretinoin*, 333 NEW ENG. J. MED. 101, 102 (1995); *id.* at 104–05 (concluding that the system had worked fairly well, though estimating that less than half of treated women had enrolled); *see also* FDA, General Information About Pregnancy Exposure Registries, http://www.fda.gov/ScienceResearch/SpecialTopics/WomensHealthResearch/ucm134844.htm (last visited Mar. 5, 2010); Margaret A. Honein et al., *Can We Ensure the Safe Use of Known Human Teratogens?: Introduction of Generic Isotretinoin in the US as an Example*, 27 DRUG SAFETY 1069, 1073 (2004) (discussing a voluntary pregnancy registry for antiepileptic drugs). The FDA demanded a similar tracking requirement when it approved Thalomid® (thalidomide) for limited use. *See* Rita Rubin, *Thalidomide Could Guide Use of Drugs That Risk Birth Defects*, USA TODAY, July 22, 1998, at 7D; Sheryl Gay Stolberg, *Thalidomide Approved to Treat Leprosy, with Other Uses Seen*, N.Y. TIMES, July 17, 1998, at A1.

59. *See* Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901(a), 121 Stat. 823, 923 (to be codified at 21 U.S.C. § 355(o)(3)(D)); *see also id.* § 905, 121 Stat. at 944 (to be codified at 21 U.S.C. § 355(k)(3)(C)(i)(III)(aa)) (directing the agency to tap into existing public databases such as that of the Medicare program); Barry Meier, *House Bill Would Create Artificial Joints Registry*, N.Y. TIMES, June 11, 2009, at B3.

60. *See* Cindy Skrzycki, *For Now, Toy-Recall Registration Isn't in the Cards*, WASH. POST, Mar. 11, 2003, at E1.

61. *Cf.* Carnahan, *supra* note 22, at 230 n.7 ("To the extent that [Medicare] coverage is contingent upon patients providing additional (beyond billing) information to a registry for research purposes, CAD may raise some of the same issues regarding voluntary informed consent that are raised with [CSP]."); Meredith Wadman, *Medicare Compels Heart Patients to Enlist in Follow-up Research*, 433 NATURE 341 (2005) (quoting Art Caplan's objection); Michael Kranish, *New Use Is Found for Thalidomide: Fighting Cancer*, BOSTON GLOBE, Oct. 20, 2002, at A28 (reporting objections to Boston University's initial policing role: "[T]he Office of Human Research Protections . . . said that if patients could lose their medicine for not responding to the BU survey, that 'failed to minimize the possibility of coercion or undue influence as required by [HHS].'").

62. *See* Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110–85,

patients to enroll in such studies.

II. FLAWS IN DEFENSES OF MEDICARE'S RESEARCH POLICY

This Part focuses on the ethical questions posed by Medicare's CSP policy, comparing and contrasting previously described instances of arguably nonconsensual research undertaken by or at the behest of the DOD and the FDA. In particular, this Part critically evaluates published defenses of CMS's approach, and it asks more broadly what such arguments may have to tell us about the nature and direction of bioethics in this country. Medicare beneficiaries who enroll in RCTs hoping to access new medical technologies do not genuinely volunteer to serve as research subjects; CSP proponents who cavalierly dismiss ethical objections to this policy have in mind a fundamentally different regime of human research protections than prevails at the present time.

A. Disregarding Concerns About Volitional Impairment

For the most part, past instances of objectionable research with humans have involved failures to disclose information.[63] If individuals do not know that they have become experimental subjects, then sponsors of the research clearly have failed to secure informed consent.[64] Even in the absence of deception, however, subjects may object if their participation was nonconsensual. At its core, informed consent requires both knowledge and volition,[65] and research violates these norms where subjects participate

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§ 901, 121 Stat. 823, 922 (to be codified at 21 U.S.C. § 355(o)(3)); Charles Steenburg, *The Food and Drug Administration's Use of Postmarketing (Phase IV) Study Requirements: Exception to the Rule?*, 61 FOOD & DRUG L.J. 295, 325–27 (2006); Jennifer Corbett Dooren, *Drug Makers Seen as Slow to Finish Postmarket Studies*, WALL ST. J., June 1, 2005, at D4.

63. *See, e.g.*, Henry K. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966) (discussing twenty-two examples of research studies conducted without consent of the subjects); William J. Curran, *The Tuskegee Syphilis Study*, 289 NEW ENG. J. MED. 730 (1973); Barron H. Lerner, *Sins of Omission—Cancer Research Without Informed Consent*, 351 NEW ENG. J. MED. 628, 629–30 (2004); Lawrence K. Altman, *Fatal Drug Trial Raises Questions About 'Informed Consent,'* N.Y. TIMES, Oct. 5, 1993, at C3; Marlene Cimons, *CDC Says It Erred in Measles Study*, L.A. TIMES, June 17, 1996, at A11; Sandy Rovner, *Ethics Concerns Raised in Schizophrenia Study*, WASH. POST, Sept. 29, 1992, at F7; *see also supra* note 24 (referencing secret radiation experiments).

64. *See generally* JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE (2d ed. 2001); Karine Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157 (1998).

65. *See* RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT 238–39, 256–57 (1986); *id.* at 337 ("Disclosing, informing, and comprehending are the most widely discussed topics in traditional commentary on informed consent. But remaining independent of control by others is equally important for autonomous decisionmaking."); NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL AND

knowingly but involuntarily.[66]

Consent, which expresses an individual's decision to volunteer to serve as an experimental subject, is widely recognized as the central ethical requirement for conducting clinical research. In its very first sentence, the Nuremberg Code insisted on "voluntary consent," with affiliated demands for adequate disclosure of information mentioned only secondarily.[67] Similarly, the International Covenant on Civil and Political Rights emphasized that "no one shall be subjected without his *free consent* to medical or scientific experimentation."[68] It may be easier to discern and

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POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS 98–99 (2001), http://bioethicsprint.bioethics. gov/reports/past_commissions/nbac_human_part.pdf; Benjamin Freedman, *A Moral Theory of Informed Consent*, HASTINGS CTR. REP., Aug. 1975, at 32, 35–37; Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 900 (1994) ("To say that one cannot be bound by a promise that one did not voluntarily and knowingly make is to say that the individual should be the author of her own undertakings, that a genuine respect for her dignity requires a broad deference to her choices.").

66. *See, e.g.*, Blanton v. United States, 428 F. Supp. 360, 361–63 (D.D.C. 1977) (imposing tort liability on a government hospital for administering an FDA-approved drug to a patient as part of a clinical trial to determine its effectiveness beyond the labeled shelf life after the patient had specifically declined to participate as a subject). *See generally* Robert M. Nelson & Jon F. Merz, *Voluntariness of Consent for Research: An Empirical and Conceptual Review*, 40 MED. CARE V-69 (2002).

67. Although it was only one of ten principles enunciated in the Nuremberg Code, consent received top billing:

> The *voluntary consent* of the human subject is *absolutely essential*. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to *exercise free power of choice*, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have *sufficient knowledge* and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment.

The Nuremberg Code (1947), *reprinted in* 276 JAMA 1691 (1996) (emphasis added); *see also* Evelyne Shuster, *Fifty Years Later: The Significance of the Nuremberg Code*, 337 NEW ENG. J. MED. 1436, 1439 (1997). *But cf.* Ezekiel J. Emanuel et al., *What Makes Clinical Research Ethical?*, 283 JAMA 2701, 2701–02 (2000) (noting "the near obsession with autonomy in US bioethics," but cautioning that the Nuremberg Code and other ethical guidelines "were written in response to specific events" and therefore "tend to emphasize certain ethical requirements while eliding others"); *id.* at 2706 (discussing consent).

68. International Covenant on Civil and Political Rights art. 7, Dec. 16, 1966, 999 U.N.T.S. 171, 175 (1976) (emphasis added). The Declaration of Helsinki made voluntary participation one of many requirements for research. *See* WORLD MED. ASS'N DECLARATION OF HELSINKI, ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS ¶ 22 (2008),

criticize instances of inadequate disclosure, but we also must guard against situations where researchers take advantage of the constrained choices available to fully informed individuals.

A handful of commentators have questioned the ethical propriety of Medicare's CSP policy.[69] The most focused discussion of the issue, however, offered a thorough-going defense of the approach. An article published in the *Journal of the American Medical Association* (*JAMA*) by Steven Pearson and colleagues from NIH's Department of Clinical Bioethics—Ezekiel Emanuel and Franklin Miller—found much to praise and little to criticize in this "bold initiative by the CMS to use its considerable power as a public insurer to promote efforts to improve the evidence available on critical clinical questions for many health care decision makers."[70] Considerable power indeed!

After pointing out that some CEDs such as patient registries may not qualify as "research" in the first place, Pearson et al. rightly conceded that CSPs unmistakably fall within the category.[71] When a treatment

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http://www.wma.net/en/30publications/10policies/b3/17c. pdf; *see also id*. ¶ 24 (calling for "freely-given" consent only after specifying the need for adequate disclosures of information); George J. Annas, *The Legacy of the Nuremberg Doctors' Trial to American Bioethics and Human Rights*, 10 MINN. J.L. SCI. & TECH. 19, 24 & n.19 (2009) (describing the Declaration of Helsinki as designed to offer a more flexible set of ethical guidelines than the rigid and legalistic Nuremberg Code); *id*. at 23–26 (explaining that bioethics originated with the Code); Troyen A. Brennan, *Proposed Revisions to the Declaration of Helsinki—Will They Weaken the Ethical Principles Underlying Human Research?*, 341 NEW ENG. J. MED. 527 (1999) (cautioning against a turn toward utilitarianism).

69. *See, e.g.*, Carnahan, *supra* note 22, at 232 (calling CSP "ethically problematic"); *id*. at 262–66; *id*. at 268 (concluding that CSP likely "violates the federal regulations for the protection of human subjects"); *id*. at 270–71 (defending CAD as a preferable approach). Ms. Carnahan's article focused, however, on questions about whether CMS enjoyed the statutory authority to impose such a coverage requirement, and she made no effort to confront ethical defenses of the program authored by its primary architects.

70. Steven D. Pearson et al., *Medicare's Requirement for Research Participation as a Condition of Coverage: Is It Ethical?*, 296 JAMA 988, 990 (2006). Dr. Pearson disclosed that, "from September 2005 through June 2006, he [had] served as Special Advisor, Technology and Coverage Policy, at [CMS.]." *Id*. (Moreover, NIH and CMS are sister agencies housed within HHS that have collaborated on particular CEDs.) A subsequently published defense with one of his earlier co-authors revealed that Pearson had joined NIH's Department of Clinical Bioethics. *See* Franklin G. Miller & Steven D. Pearson, *Coverage with Evidence Development: Ethical Issues and Policy Implications*, 46 MED. CARE 746, 746 (2008). Pearson's other original co-author, Zeke Emanuel, recently left NIH to join his older brother Rahm in the White House. *See* Robert Pear, *Hard-Charging Doctor Adds Perspective to the President's Health Care Team*, N.Y. TIMES, Apr. 18, 2009, at A10.

71. *See* Pearson et al., *supra* note 70, at 989 (recognizing "active debate and disagreement among experts over whether registries and other forms of health care services research require full, partial, or no informed consent"); *id*. (conceding that some CEDs "have linked coverage to studies that all would acknowledge are research"). According to the authors: "In a registry, all eligible patients receive the treatment, and in most registries

relationship gets converted into part of a clinical trial, the patient becomes a "subject" (and the physician becomes an "investigator");[72] the subject may or may not receive the investigational intervention—randomization and blinding make the assignment a matter of chance and secrecy—and probably will have to undergo more frequent follow-up monitoring than normal.[73] Given these features of research, it becomes critical to determine whether a subject has volunteered.

Pearson et al. also conceded that, "[a]lthough CED is clearly well-intentioned, it raises several important ethical questions."[74] As they saw it, however, these questions boil down to asking whether conditioning Medicare coverage on enrollment in a clinical trial amounts to "coercion,"[75] and they concluded that it does not because (1) beneficiaries

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patients face minimal additional research burdens while often benefiting from the information gained." *Id.*; *see also* Ancheff v. Hartford Hosp., 799 A.2d 1067, 1071–72, 1082 (Conn. 2002) (affirming a jury's conclusion that a hospital's protocol for off-label use of an antibiotic did not qualify as research); Hecht v. Kaplan, 645 N.Y.S.2d 51, 53 (App. Div. 1996) (rejecting the plaintiff's claim that the decision to perform an additional diagnostic test on a sample of her blood amounted to experimentation without consent in violation of state statute); *cf.* Schwartz v. Boston Hosp. for Women, 422 F. Supp. 53, 55–56 (S.D.N.Y. 1976) (denying a motion for summary judgment on plaintiff's claim that she had not consented to an experimental procedure, though she had agreed to the use of records concerning her obstetrical treatment at a hospital participating in a national study of pregnant diabetics, because the court found "a fact question of whether the curettage was performed for purposes of the MIH study rather than to aid in the diagnosis and treatment of Mrs. Schwartz"). *See generally* Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J.L. & MED. 361, 403–04 (2002). For suggestions that even patient registries may raise ethical concerns, see *supra* note 61 and accompanying text.

72. *See* Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 7, 15–16, 33 (1993); Franklin G. Miller et al., *Professional Integrity in Clinical Research*, 280 JAMA 1449, 1450–51 (1998).

73. *See* Donna T. Chen et al., *Clinical Research and the Physician–Patient Relationship*, 138 ANNALS INTERNAL MED. 669, 669 (2003) (explaining that "participation in some trials may include medication washout periods, biopsies, overnight hospital stays, imaging studies, blood draws, and questionnaires"); Jesse A. Goldner, *An Overview of Legal Controls on Human Experimentation and the Regulatory Implications of Taking Professor Katz Seriously*, 38 ST. LOUIS U. L.J. 63, 121–22 (1993); Franklin G. Miller, *Research Ethics and Misguided Moral Intuition*, 32 J.L. MED. & ETHICS 111, 112 (2004); Franklin G. Miller & Donald L. Rosenstein, *The Therapeutic Orientation to Clinical Trials*, 348 NEW ENG. J. MED. 1383, 1383 (2003); E. Haavi Morreim, *The Clinical Investigator as Fiduciary: Discarding a Misguided Idea*, 33 J.L. MED. & ETHICS 586, 587, 589–90 (2005).

74. Pearson et al., *supra* note 70, at 989.

75. The authors separately defended the fairness of CED in instances where required patient registries or RCTs may not exist in certain parts of the country. *See id.* ("Inequality in access to research programs is a regrettable practical reality but does not constitute an injustice."); *id.* at 990 ("[W]ithout CED there would be no coverage at all, so inconsistent access to the technology after CED, while not ideal, is not unethical. Unequal access is not remedied by denying opportunities for all."). Inequities may, however, arise for reasons unrelated to limited geographic coverage. *See* Carnahan, *supra* note 22, at 259 (discussing

would remain free to secure access without enrolling in a study if willing to pay out of pocket,[76] and (2) beneficiaries had no right to expect any coverage in the first place.[77] This pair of assumptions led the authors to conclude that the CED approach represented a win–win situation,[78] but neither premise withstands close scrutiny.

First, the notion that Medicare patients remain free to access items and services in the open market pays insufficient attention to the financial circumstances confronting most beneficiaries.[79] It would seem equally implausible to defend research using persons in poor countries by noting that they could have paid out of pocket for the health care intervention under investigation. One decade ago, placebo-controlled trials of human immunodeficiency virus (HIV) drugs in developing countries generated tremendous controversy—defenders of the research did not make the absurd point that subjects theoretically had the option of purchasing antiretrovirals; instead, they argued that subjects given a fifty percent chance of receiving drug treatment were better off than they otherwise would have been precisely because affordability barriers made it impossible for the vast majority of patients to get such treatments.[80] Whatever one

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restrictive enrollment criteria that would exclude beneficiaries with co-morbidities and result in underpowered trials).

76. *See* Pearson et al., *supra* note 70, at 988–89.

77. *See id*. at 988 ("CED should not be viewed as coercive because Medicare patients are not entitled to new technologies that would not receive coverage in the absence of CED."); *id*. ("Before CED, therefore, evidence that did not quite reach the CMS interpretation of 'reasonable and necessary' routinely led to a denial of coverage for a new technology."); *id*. at 989 ("Medicare explicitly conveys no entitlement to insurance coverage for all new technologies, only to those technologies judged by the CMS to be 'reasonable and necessary.'"); *id*. ("[C]overage has always been routinely denied for technologies that fail to meet Medicare's interpretation of its evidentiary standards. Without CED, coverage denial would thus be the common fate of these technologies.").

78. *See id*. at 989 ("CED was designed so that patients would gain earlier access to promising but as yet unproven technologies, industry would receive payment for innovations that would not have been covered otherwise, and all health care decision makers would benefit from the generation of better evidence on the true risks, benefits, and costs.").

79. *See* Carnahan, *supra* note 22, at 235; *id*. at 265 ("Given the high cost of new health care technology, no realistic possibility of private purchase exists."); *see also* Emily Brandon, *Even with Medicare, Health Costs Pack a Wallop*, ORLANDO SENT., Mar. 11, 2010, at G2; Deborah Thorne et al., *The Increasing Vulnerability of Older Americans: Evidence from the Bankruptcy Court*, 3 HARV. L. & POL'Y REV. 87, 100 (2009); *New Formula Shows More Live in Poverty*, BOSTON GLOBE, Oct. 21, 2009, at A2 ("About 18.7 percent of Americans 65 and older, or nearly 7.1 million, are in poverty . . . ."). Insofar as CMS effectively exercises a monopoly over the health care options available to the elderly, the agency's use of that power to encourage study participation would differ little from the leverage that the Federal Bureau of Prisons might enjoy if it wanted to promote research by conditioning inmates' access to particular health services on their willingness to enroll in RCTs. *See infra* note 125 (discussing research on prisoners).

80. *See* David P. Fidler, *"Geographical Morality" Revisited: International Relations, International*

may think about their ethical propriety, the overseas HIV drug trials clearly raised eyebrows among many in the research community, while similarly structured trials involving American seniors evidently have not attracted much notice.

Second, the noncoverage baseline that Pearson et al. assumed suffers from an inevitable contingency. One CED announced shortly before CMS formulated its draft guidance represented an instance where the agency had refused coverage before intense lobbying forced it to accept conditional coverage as a compromise.[81] Historically, however, the precise criteria used in making Medicare coverage decisions—whether local or national—have proven difficult to discern.[82] Perhaps CED provides the agency with a useful half-step toward coverage in close cases, but, in the absence of this option, it seems equally likely that CMS would allow coverage,[83] deferring to the judgments of physicians[84] and local contractors,[85] unless and until it

Law, and the Controversy over Placebo-Controlled HIV Clinical Trials in Developing Countries, 42 HARV. INT'L L.J. 299, 306–13 & n.82 (2001); David Orentlicher, *Universality and Its Limits: When Research Ethics Can Reflect Local Circumstances*, 30 J.L. MED. & ETHICS 403, 404–07 (2002); Harold T. Shapiro & Eric M. Meslin, *Ethical Issues in the Design and Conduct of Clinical Trials in Developing Countries*, 345 NEW ENG. J. MED. 139, 140 (2001).

81. *See* Rick Weiss, *A Tale of Politics: PET Scans' Change in Medicare Coverage*, WASH. POST, Oct. 14, 2004, at A1.

82. *See* Medicare Program; Revised Process for Making Medicare National Coverage Decisions, 68 Fed. Reg. 55,634 (Sept. 26, 2003); Medicare Program; The National and Local Coverage Determination Review Process, 66 Fed. Reg. 54,253 (Oct. 26, 2001); Susan Bartlett Foote, *Why Medicare Cannot Promulgate a National Coverage Rule: A Case of* Regula Mortis, 27 J. HEALTH POL. POL'Y & L. 707, 711–12, 715–20 (2002); Muriel R. Gillick, *Medicare Coverage for Technological Innovations—Time for New Criteria?*, 350 NEW ENG. J. MED. 2199, 2202 (2004); Sean R. Tunis, Editorial, *Why Medicare Has Not Established Criteria for Coverage Decisions*, 350 NEW ENG. J. MED. 2196 (2004); *see also* Eleanor D. Kinney, *Medicare Coverage Decision-Making and Appeal Procedures: Can Process Meet the Challenge of New Medical Technology?*, 60 WASH. & LEE L. REV. 1461, 1471–72 (2003); *id.* at 1462 ("Medicare coverage policy for new medical technology has been a very controversial issue in the administration of the Medicare program since its inception."); *id.* at 1501 ("[T]he development of criteria for making coverage decisions has been a very intractable issue for the Medicare program since coverage surfaced as a serious policy issue in the 1980s.").

83. *See, e.g.*, Reed Abelson, *Heart Scans Still Covered by Medicare*, N.Y. TIMES, Mar. 13, 2008, at C1 (reporting that CMS dropped its earlier proposal to impose a CSP requirement on cardiac computed tomography angiography even though it remained skeptical about the usefulness of the procedure); Barnaby J. Feder, *U.S. Expands Some Stent Reimbursement Coverage*, N.Y. TIMES, Mar. 18, 2005, at C4 (reporting that Medicare broadened payment for carotid stenting six months after the FDA approved the first device for use in this procedure); Antonio Regalado, *Who Gets Health Care? Rationing in an Age of Rising Costs*, WALL ST. J., Sept. 18, 2003, at A1 (reporting that CMS took the unprecedented step of granting "new technology" status to the drug Xigris® (drotrecogin alfa), which authorized federal reimbursement for half of the cost of this expensive new treatment for sepsis).

84. *See* Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 165–66 (2004) (discussing Medicare's codified noninterference principle).

later concluded that new evidence cast doubt on the safety and efficacy of the medical intervention.[86]

Indeed, later in their article, Pearson et al. emphasized that CMS should use CED in only a fairly narrow range of circumstances: "ethical application of CED requires that clear criteria exist by which technologies can be identified as fitting into an evidentiary middle ground, one that might be called 'promising but unproven.'"[87] This caveat has far less to do with ethical than statutory constraints because, if "proven," then a new technology presumptively secures coverage, and "proof" has never before required the elimination of all residual uncertainty much less answers to questions entirely collateral to the value of an intervention in treating patients. Moreover, precisely because of the possibility of "underappreciated risks" with "promising but unproven" technologies,[88] CMS should endeavor to secure genuinely informed consent when using its CED policy. The authors also, however, attempted to justify extending CED to what might be called "proven but expensive" new technologies,[89]

85. *See, e.g.*, Stephanie Saul, *(Not So) Standard Procedure*, N.Y. TIMES, Dec. 17, 2008, at B1 (reporting uneven coverage decisions for CyberKnife, a device for treating prostate cancer, adding that "[t]he disparities result from a policy principle as old as Medicare itself, in which officials in Washington leave many reimbursement decisions to the discretion of 15 regional contractors around the country"); *id.* ("[O]ver the years, Medicare has resolved only about 300 such [new technology] questions with blanket national coverage rulings. Meanwhile, thousands of other coverage policies have been—and continue to be—decided region by region.").

86. *See, e.g.*, Gina Kolata, *A Study Revives a Debate on Arthritis Knee Surgery*, N.Y. TIMES, Sept. 11, 2008, at A19 (reporting that Medicare had stopped covering arthroscopic surgery for arthritis of the knee in 2003 after a study sponsored by Department of Veterans Affairs found no benefit); *see also* Denise Grady, *Studies Question Using Cement for Spine Fractures*, N.Y. TIMES, Aug. 6, 2009, at A18 ("Medicare had no national policy on vertebroplasty and had been letting states decide. They have been covering it."); *id.* ("Dr. Salive said Medicare had looked into the treatment in 2005 but found a lack of [RCTs]. . . . [I]t was too soon to tell whether the [latest negative] research would affect coverage.").

87. Pearson et al., *supra* note 70, at 990 ("This middle ground must not be so broad as to include almost any new technology . . . ."); *see also id.* at 988 ("The CMS designed CED as a coverage mechanism that could be used when promising evidence suggested that patients might benefit from a new technology, but additional evidence was needed to determine with confidence that the technology met Medicare's statutory standard for coverage . . . ."); *id.* at 990 ("[CED] is based on identifying technologies for which the supporting evidence is not strong enough to warrant an entitlement to unlimited coverage."). This suggests that CMS could not legitimately use CED solely for purposes of acquiring collateral information about older—or clearly proven newer—technologies.

88. *Id.* at 990 ("A full analysis of the ethics of CED must not ignore the possibility that CED could result in the premature and inflated use of technologies that have underappreciated risks for many patients.").

89. *See id.* ("If a new technology with 'promising' evidence would be extremely expensive if used widely without further definition of its true risks and benefits, further ethical weight would be added to the rationale for requiring evidence development as a

which aptly describes the latest CSP: genetic testing before use of warfarin does not pose any unresolved questions of safety or efficacy; instead, it confronts CMS with practical questions of affordability given uncertainties about incremental clinical utility.[90]

B. Confining the Inquiry to "Coercion" Strictly Construed

Pearson et al. use a cramped notion of coercion as existing only when threats of adverse consequences override the exercise of genuinely free choice. Citing Wertheimer's classic treatment of the subject,[91] and apparently unaware of his subsequent book devoted to the closely related matter of "exploitation,"[92] they explained that "[c]oercion occurs when a threat of some harm compels a person to act in a manner that he or she

condition of coverage."); *id.* ("[S]ince CED cannot for practical reasons be used as the coverage approach for all 'promising' technologies, cost considerations should play a valid and honest role in selecting which technologies should be prioritized for CED."); *see also* Kinney, *supra* note 82, at 1500 ("[O]ften there is a range of opinions on coverage of a medical technology depending on views of scientific evidence, costs and other factors. Ultimately, a coverage decision is a political decision that balances many factors. There really is no 'accurate' decision regarding a disputed coverage issue.").

90. *See supra* notes 17–19 and accompanying text. These are legitimate and difficult questions, and CED allows Medicare to take it slowly, but such concerns hardly justify a requirement for enrollment in clinical trials—instead, CMS candidly should admit that only a fraction of those interested in access to an expensive new technology can receive it, at least until additional information demonstrates its value. In other contexts requiring the allocation of scarce health care resources, providers have utilized various selection methods. *See* Ezekiel J. Emanuel & Alan Wertheimer, *Who Should Get Influenza Vaccine When Not All Can?*, 312 SCIENCE 854 (2006); Lawrence O. Gostin, *Medical Countermeasures for Pandemic Influenza: Ethics and the Law*, 295 JAMA 554 (2006); Lars Noah, *Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. REV. 741, 754–57 (2003).

91. ALAN WERTHEIMER, COERCION (1987).

92. ALAN WERTHEIMER, EXPLOITATION (1996). In fact, Pearson's co-authors previously had discussed this work, though at times giving it an unduly narrow interpretation. *See* Jennifer S. Hawkins & Ezekiel J. Emanuel, *Clarifying Confusions About Coercion*, HASTINGS CTR. REP., Sept.–Oct. 2005, at 16, 19 & n.12; *see also* Franklin G. Miller & Howard Brody, *A Critique of Clinical Equipoise: Therapeutic Misconception in the Ethics of Clinical Trials*, HASTINGS CTR. REP., May–June 2003, at 19, 26 (noting "the core value of *protecting research participants from exploitation*"); *cf.* David B. Resnik, *Exploitation in Biomedical Research*, 24 THEORETICAL MED. 233, 236 (2003) ("[H]arm is not a necessary condition for exploitation because exploitation may occur without any harm to the exploitee. Exploitation can occur when the exploiter fails to show adequate respect for the dignity or autonomy of the exploitee."); *id.* at 242 ("[I]n recent debates about the ethics of human research, . . . many different authors have made the charge of exploitation without explaining what they mean by this word or how we should respond to this accusation."); *id.* at 252 ("[E]xploitative research may be still ethical under some circumstances. Indeed, it is likely that a great deal of biomedical research is minimally exploitative yet still morally justified."). As it happens, Wertheimer recently joined the NIH's Department of Bioethics.

would not otherwise choose."[93] Pearson et al. distinguished coercion from "compulsion" as if that marked an ethically relevant boundary line:

> It might be argued that CED is coercive because some patients might feel that to get the treatment they "need," they have no other option but to participate in research, although they would not choose to do so if insurance coverage did not require that participation. But feeling compelled to participate in research does not constitute coercion. Some patients with terminal cancer, because of their dire prognosis, may feel compelled to enter phase I research studies, but making such a choice, even though it is done under difficult circumstances and with limited options, does not constitute coercion. Coercion requires a person, organization, or policy to threaten specific "harm."[94]

They concluded their treatment of this issue as follows: "Patients contemplating their treatment options under CED may face tough choices and may feel compelled to participate in research, but they do not do so under a cloud of coercion."[95]

Even if not technically coercion, compulsion also seems to be worrisome,[96] at least where government policy aims to take advantage of

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93. Pearson et al., *supra* note 70, at 989 (adding that "no published articles have addressed coercion in relation to insurance coverage"). "An example is that of a kidnapper demanding ransom. The kidnapped victim's family may be coerced into giving up money to avoid the threatened harm to their loved one." *Id.* So coercion to participate in research would arise only in entirely implausible circumstances such as where an investigator secures "consent" by threatening a subject with violence?! *Cf.* Hawkins & Emanuel, *supra* note 92, at 19 ("Researchers standardly make *offers* to potential subjects, not threats.").

94. Pearson et al., *supra* note 70, at 989 (endnote omitted). The authors elaborated as follows:

> It could be argued . . . that CED threatens patients with a specific harm—the withholding of unrestricted insurance coverage. If obtaining coverage for a new technology without any requirement for research participation is the "best" option for patients, any policy short of unfettered access might represent a harm and be coercive. However, this argument is unsound. The fact that patients might feel entitled to the "best" option does not mean that they are entitled.

Id. ("Because CED does not propose to deny coverage to a technology to which patients are entitled, it does not threaten them with any harm. Since there is no threat of harm, concerns that CED is coercive are mistaken or misplaced.").

95. *Id.*; *see also* Manish Agrawal & Ezekiel J. Emanuel, *Ethics of Phase 1 Oncology Studies: Reexamining the Arguments and the Data*, 290 JAMA 1075, 1080–81 (2003). *But cf.* D. Christian Addicott, *Regulating Research on the Terminally Ill: A Proposal for Heightened Safeguards*, 15 J. CONTEMP. HEALTH L. & POL'Y 479 (1999) (urging that such patients be treated as a vulnerable class); Goldner, *supra* note 73, at 130 n.414 ("[T]he fact that [RCT enrollment] may well be the only avenue for obtaining such a benefit [of access to otherwise unavailable treatment] could be viewed as a form of inherent coercion that would vitiate the voluntariness of any consent that might be obtained."); Jerry Menikoff, *The Vulnerability of the Very Sick*, 37 J.L. MED. & ETHICS 51 (2009); Brendan P. Minogue et al., *Individual Autonomy and the Double-Blind Controlled Experiment: The Case of Desperate Volunteers*, 20 J. MED. & PHIL. 43, 46–52 (1995).

96. *See* Paul S. Appelbaum et al., *Voluntariness of Consent to Research: A Conceptual Model*,

vulnerable patients' circumstances.[97] This feature (namely, state action) would serve to distinguish their cancer example. Although private sponsors of RCTs have no greater license to engage in nonconsensual research,[98] they have absolutely no incentive to drag out drug trials in order to maintain a pool of patients desperate to enroll.[99] Perhaps the FDA's entire system of licensure, which withholds approval until sponsors have undertaken adequate studies, creates the same pressure on patients anxious for early access,[100] though the nonavailability baseline in this context lacks

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HASTINGS CTR. REP., Jan.–Feb. 2009, at 30, 34–36 (discussing problematic offers and pressures as distinct from threats); *see also id.* at 37 ("[V]oluntariness occurs along a spectrum. Since subjects more often than not offer multiple reasons for enrollment, drawing a line between voluntary and involuntary actions is often not easy."); *cf. id.* ("[A] threat to withhold the patient's Social Security disability check unless she agrees to enter a study is clearly unacceptable."). *See generally* Alan Wertheimer, *Remarks on Coercion and Exploitation*, 74 DENV. U. L. REV. 889, 890–92, 894 (1997); *id.* at 896 ("[I]n the final analysis I do not believe that much turns on whether we can legitimately say that one agreement or another is exploitative or coercive on some linguistically plausible account of these terms."); *id.* at 906 ("We can call A's offer coercive and/or exploitative, but such labels will not resolve that moral problem. Having said that, it does not follow that the best moral answer is always to allow A to propose and B to accept any proposal that would be advantageous to B and rational for B to accept."). Wertheimer offered almost two dozen brief illustrations, including one involving experimentation with prisoners, *see id.* at 895–96, which he then alluded to in the remainder of his article, *see id.* at 896–906. Wertheimer made only passing and largely equivocal subsequent references to the experimentation hypothetical, *see id.* at 900–05, and his conclusion expressed doubts about prohibiting such research, *see id.* at 906. For further discussion of existing limitations on experimentation with prisoners, see *infra* note 125.

97. *Cf.* Carnahan, *supra* note 22, at 261–62 (arguing that elderly patients may experience particular difficulties understanding consent forms and represent an especially vulnerable population); Robert L. Schwartz, *Informed Consent to Participation in Research Employing Elderly Human Subjects*, 1 J. CONTEMP. HEALTH L. & POL'Y 115, 126–27 (1985) (elaborating on the vulnerability of nursing home residents to coercion); Donna Shalala, *Protecting Research Subjects—What Must Be Done*, 343 NEW ENG. J. MED. 808, 808 (2000) (describing a "case of a woman in a nursing home who was allegedly forced to participate in a study under threat of expulsion from the home").

98. Apart from the threat of regulatory sanctions, private researchers who injure subjects may face tort claims. *See, e.g.*, Sharona Hoffman & Jessica Wilen Berg, *The Suitability of IRB Liability*, 67 U. PITT. L. REV. 365 (2005); Michelle M. Mello et al., *The Rise of Litigation in Human Subjects Research*, 139 ANNALS INTERNAL MED. 40 (2003); E. Haavi Morreim, *Litigation in Clinical Research: Malpractice Doctrines Versus Research Realities*, 32 J.L. MED. & ETHICS 474, 475, 479–80 (2004); Roger L. Jansson, Comment, *Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions*, 78 WASH. L. REV. 229 (2003).

99. *See* Lars Noah, *Sham Petitioning as a Threat to the Integrity of the Regulatory Process*, 74 N.C. L. REV. 1, 2 n.3 (1995) (noting that even one month delay in market entry could cost a drug company $10 million).

100. *See* Richard A. Epstein, *The Erosion of Individual Autonomy in Medical Decisionmaking: Of the FDA and IRBs*, 96 GEO. L.J. 559, 579–80 (2008); Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813, 1830 n.81 (2007) ("[S]ociety would balk at a law that generally forced people to go into clinical trials,

the contingency of Medicare's supposed noncoverage baseline: Congress insisted that new drugs not reach the market unless and until adequate and well-controlled studies satisfied the FDA that the product was relatively safe and effective.[101]

If, however, the FDA unreasonably withheld approval in order to force sponsors to engage in additional studies,[102] then these two situations become harder to distinguish. No doubt the agency would defend itself by pointing out that (1) patients have no right of access to unapproved medical technologies,[103] and (2) patients may secure access by other means (for instance, from other countries).[104] Indeed, because of various exceptions adopted by the FDA over the last two decades under pressure from desperate acquired immunodeficiency syndrome (AIDS) and cancer patients, individuals have several ways of securing access to investigational products without enrolling in RCTs (and without having to pay retail when their health insurers invoke experimental exclusion clauses).[105] Would

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and a law that forces people to go into clinical trials if they want access to the only possibly lifesaving drugs seems to be no less coercive."). As an illustration of the power of this inducement, when private research sponsors discontinue RCTs, subjects have brought litigation in an effort to secure continued access to investigational products. *See, e.g.*, Abney v. Amgen, Inc., 443 F.3d 540, 550–53 (6th Cir. 2006) (rejecting such claims); Dahl v. HEM Pharms. Corp., 7 F.3d 1399, 1404–05 (9th Cir. 1993) (holding that the plaintiffs had a contract claim entitling them to an additional one-year supply); *see also* Michael M. Grynbaum, *Judge Orders Drug Maker to Provide Experimental Treatment to Terminally Ill Teenager*, N.Y. TIMES, Aug. 21, 2008, at C3.

101. *See* 21 U.S.C. § 355 (2006); United States v. Rutherford, 442 U.S. 544, 557–58 (1979). Congress recently directed the FDA to give expanded access to unapproved drugs for individuals suffering from serious diseases, but only if doing so would not impair the conduct of preapproval clinical trials. *See* 21 U.S.C. § 360bbb(b)(3), (c)(5).

102. *Cf.* Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 577–78, 583–85 (2001) (discussing delays in the approval of RU-486); Lars Noah, *Treat Yourself: Is Self-Medication the Prescription for What Ails American Health Care?*, 19 HARV. J.L. & TECH. 359, 374–76 & n.91 (2006) (discussing FDA delays in approving the switch of emergency contraceptives to nonprescription status); Lawrence S. Makow, Note, *Medical Device Review at the Food and Drug Administration: Lessons from Magnetic Resonance Spectroscopy and Biliary Lithotripsy*, 46 STAN. L. REV. 709, 730–32 (1994) (objecting to the agency's demands for additional studies of devices used to treat gallstones).

103. *See* Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695 (D.C. Cir. 2007) (en banc); *see also* Jerry Menikoff, *Beyond* Abigail Alliance*: The Reality Behind the Right to Get Experimental Drugs*, 56 U. KAN. L. REV. 1045 (2008); Alissa Puckett, Comment, *The Proper Focus for FDA Regulations: Why the Fundamental Right to Self-Preservation Should Allow Terminally Ill Patients with No Treatment Options to Attempt to Save Their Lives*, 60 SMU L. REV. 635 (2007).

104. *See* Peter S. Reichertz & Melinda S. Friend, *Hiding Behind Agency Discretion: The Food and Drug Administration's Personal Use Drug Importation Policy*, 9 CORNELL J.L. & PUB. POL'Y 493, 501–02 (2000); Mary Pat Flaherty & Gilbert M. Gaul, *Millions of Americans Look Outside U.S. for Drugs*, WASH. POST, Oct. 23, 2003, at A1 (reporting that the agency largely fails to enforce the policy's limitations).

105. *See* 21 U.S.C. § 360bbb (2006); 21 C.F.R. § 312.34 (2009); Steven R. Salbu, *The*

either one of these rebuttals answer ethical objections to the FDA's hypothetical policy of delaying licensure of safe and effective products in order to ensure that desperate patients continue to enroll in ongoing RCTs?

CMS could, of course, simply deny coverage if unpersuaded by the available evidence (as Pearson et al. argued it would do if unable to make use of the CED option), which would leave proponents to sponsor additional research that eventually might change the agency's mind.[106] Alternatively, CMS could defer making a coverage determination and ask another federal agency to undertake additional research (indeed, the agency cited this power as giving it the statutory authority for the CSP policy).[107] In either case, the existing policy of covering incidental costs of Medicare beneficiaries enrolled as subjects would facilitate completion of such studies, but the cost of the investigational item or service would fall on the sponsor.[108] From the standpoint of beneficiaries seeking access to a new but not yet covered medical intervention, the incentives seem identical (enroll or pay in full); from the standpoint of CMS, especially if it underwrites the research, the outcome seems largely the same. Nonetheless, ethically these may not come to exactly the same thing insofar

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FDA and Public Access to New Drugs: Appropriate Levels of Scrutiny in the Wake of HIV, AIDS, and the Diet Drug Debacle, 79 B.U. L. REV. 93, 113–21 (1999). Although it ultimately prevailed in the latest litigation challenging restrictions on access to investigational drugs, the FDA recently liberalized its rules. *See* Charging for Investigational Drugs Under an Investigational New Drug Application, 74 Fed. Reg. 40,872 (Aug. 13, 2009) (to be codified at 21 C.F.R. pt. 312); Expanded Access to Investigational Drugs for Treatment Use, 74 Fed. Reg. 40,900 (Aug. 13, 2009) (to be codified at 21 C.F.R. pts. 312, 316); *see also* Linda Katherine Leibfarth, Note, *Giving the Terminally Ill Their Due (Process): A Case for Expanded Access to Experimental Drugs Through the Political Process*, 61 VAND. L. REV. 1281 (2008); James P. Sikora, Note, *Providing Hope: Developing a Viable Regulatory Framework for Providing Terminally Ill Patients with Adequate Access to Investigational Drugs*, 70 U. PITT. L. REV. 191 (2008).

106. *See, e.g.*, Purva Patel, *The Word for Cyberonics Is No: Medicare Says It Won't Pay for Use of Device to Treat Depression*, HOUS. CHRON., May 5, 2007, at D1 (explaining that, although the FDA had approved the vagus nerve stimulator to treat both epilepsy and chronic depression, CMS declined to cover use of the device); Patrick Yoest, *Colon Scans Not Covered*, WALL ST. J., May 13, 2009, at D6 (reporting that CMS rejected coverage of virtual colonoscopies).

107. *See* Carnahan, *supra* note 22, at 241–42; *id.* at 269–70 (suggesting different ways of creating incentives for genuinely voluntary participation by Medicare beneficiaries in RCTs); *id.* at 269 ("CMS could also achieve its goal of generating additional data by enhancing its traditional relationship with the [Agency for Healthcare Research and Quality]."); *see also* Janet Adams et al., *Recruiting Older Adults for Clinical Trials*, 18 CONTROLLED CLINICAL TRIALS 14, 15 (1997); Thomas M. Vogt et al., *Recruitment of Elderly Volunteers for a Multicenter Clinical Trial: The SHEP Pilot Study*, 7 CONTROLLED CLINICAL TRIALS 118, 130–31 (1986) (disputing the suggestion that non-institutionalized elderly patients are difficult to recruit as subjects).

108. *See supra* notes 20–21. Of course, if CMS underwrites an RCT conducted by another agency, then it would pay for the investigational item or service as well.

as the pressure exerted on beneficiaries flows less directly from CMS.

C. Cheapening Bioethics as Legal Discourse (and Vice Versa)

One of the most striking features of the *JAMA* article by Pearson et al. has to do with its style of analysis (and tone) rather than its content. Instead of the aspirational (some would say vacuous[109]) treatment typical of bioethical issues,[110] the authors sound almost lawyerly, focusing on what seem like technicalities and semantics.[111] Conversely, as an exercise in legal analysis, their defense of the CSP policy comes across as entirely amateurish. As explained at length in the previous sections, the standard of consent to human research has more breadth than a narrow conception of coercion.

Whether understood primarily as a form of applied philosophy, an extension of professional ethics in medical practice, or as a subset of health

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109. *See* Carl E. Schneider, *After Autonomy*, 41 WAKE FOREST L. REV. 411, 412–15, 439–40 (2006); Giles Scofield, Commentary, *The Wizard of Oughts*, 28 J.L. MED. & ETHICS 232, 233–35 (2000); Michael H. Shapiro, *Is Bioethics Broke?: On the Idea of Ethics and Law "Catching up" with Technology*, 33 IND. L. REV. 17 (1999); Sheryl Gay Stolberg, *Bioethicists Find Themselves the Ones Being Scrutinized*, N.Y. TIMES, Aug. 2, 2001, at A1 (explaining that just about anyone can call themselves a "bioethicist"); *see also* Noah, *Assisted Reproductive Technologies*, *supra* note 12, at 606 ("One could criticize some of the existing academic commentary as engaging in little more than bioethical parlor games."). *See generally* JONATHAN BARON, AGAINST BIOETHICS (2006); Larry R. Churchill, *Are We Professionals? A Critical Look at the Social Role of Bioethicists*, DAEDALUS, Fall 1999, at 253; Edward J. Imwinkelried, *Expert Testimony by Ethicists: What Should Be the Norm?*, 76 TEMP. L. REV. 91 (2003).

110. *See* Robert Gatter, *Walking the Talk of Trust in Human Subjects Research: The Challenge of Regulating Financial Conflicts of Interest*, 52 EMORY L.J. 327, 383–86, 388–89 (2003) (explaining that overly prescriptive rules may weaken the tendency of researchers to "concern themselves with the normative spirit of the law"); Jeffrey P. Kahn & Anna C. Mastroianni, Commentary, *Moving from Compliance to Conscience: Why We Can and Should Improve on the Ethics of Clinical Research*, 161 ARCHIVES INTERNAL MED. 925, 925 (2001) (warning that an undue emphasis on adherence to rules "can cause researchers to quickly lose sight of the point of research protections—the rights and interests of the subjects themselves—and the protection of subjects can quickly be lost in the shuffle of paperwork necessary to satisfy the letter, if not the spirit, of regulations"); *see also* Miller et al., *supra* note 72, at 1453–54, 1449 ("[E]ven under an ideal regulatory system, the ethics of clinical research will continue to depend significantly on the integrity of investigators.").

111. Somewhat ironically, a physician who left the post of Assistant Surgeon General in 2001—and who would have played an early role in formulating the CED policy—framed the debate in the following terms: "Lawyers, often representing the technology developers or 'denied' patients, have argued that coverage with evidence development policies are coercive, unfair, and illegal. Ethicists disagree . . . ." Douglas Kamerow, *Paying for Promising but Unproven Technologies*, 335 BRIT. MED. J. 965, 965 (2007) (simply citing the *JAMA* article by Pearson et al.). Actually, NIH's own Office of Human Research Protections (OHRP) had raised questions about the CED policy, pointing out that it would have to comply with the federal regulations governing research. *See* Tunis & Pearson, *supra* note 11, at 1227.

law,[112] bioethics typically attempts to resolve questions by reference to a set of core principles rather than by splitting hairs.[113] Even more pragmatic or skeptical strains of bioethics do not cavalierly trade away commitments to autonomy and beneficence.[114] For example, in response to calls for expanded exceptions to informed consent requirements for certain types of research,[115] commentators responded in just such a guarded fashion, urging that when in doubt we always err on the side of protecting human subjects.[116]

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112. *See* Tom L. Beauchamp, *Does Ethical Theory Have a Future in Bioethics?*, 32 J.L. MED. & ETHICS 209, 216 (2004); Alexander Morgan Capron & Vicki Michel, *Law and Bioethics*, 27 LOY. L.A. L. REV. 25, 25–33 (1993); Edmund D. Pellegrino, *The Metamorphosis of Medical Ethics: A 30–Year Retrospective*, 269 JAMA 1158 (1993); Symposium, *Emerging Paradigms in Bioethics*, 69 IND. L.J. 945 (1994).

113. *See, e.g.*, Jerry Menikoff, *The Involuntary Research Subject*, 13 CAMBRIDGE Q. HEALTHCARE ETHICS 338, 340–44 (2004); *see also* ROGER B. DWORKIN, LIMITS: THE ROLE OF THE LAW IN BIOETHICAL DECISION MAKING 18 (1996) (criticizing the law's role in bioethics, and opining that "our [legal institutional] tools for dealing with social problems posed by rapid change in biology and medicine are limited at best"); Robert J. Levine, *Medical Ethics and Personal Doctors: Conflicts Between What We Teach and What We Want*, 13 AM. J.L. & MED. 351, 362 (1987) ("A focus on rights and rules . . . has a tendency to yield a 'minimalist ethics.'"); Lars Noah, *Deputizing Institutional Review Boards to Police (Audit?) Biomedical Research*, 25 J. LEGAL MED. 267 (2004) (objecting generally to the legalization of bioethics). *But cf.* Noah, *supra* note 5, at 1152–60 (splitting hairs in jest to make a point); Benedict Carey, *The Subject Is . . . Subjects*, N.Y. TIMES, June 15, 2004, at F1 (reporting that the American Psychological Association has urged the use of "participant" as a less impersonal term). Similar issues may arise in other contexts. *See* Steven R. Salbu, *Law and Conformity, Ethics and Conflict: The Trouble with Law-Based Conceptions of Ethics*, 68 IND. L.J. 101, 102, 130–31 (1992); *see also* LARS NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY: TEACHER'S MANUAL 43 (2d ed. 2007) ("[S]hould these ethical rules be construed in a lawyerly fashion or instead more capaciously to promote the broader purposes that presumably animate them?").

114. *See* Tom L. Beauchamp, *Principles and Other Emerging Paradigms in Bioethics*, 69 IND. L.J. 955, 962–66 (1994); Edmund D. Pellegrino, *Autonomy, Beneficence, and the Experimental Subject's Consent: A Response to Jay Katz*, 38 ST. LOUIS U. L.J. 55, 57–61 (1993); Susan M. Wolf, *Shifting Paradigms in Bioethics and Health Law: The Rise of a New Pragmatism*, 20 AM. J.L. & MED. 395, 396–99, 413–14 (1994). *See generally* TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (6th ed. 2009).

115. *See, e.g.*, Robert D. Truog et al., *Is Informed Consent Always Necessary for Randomized, Controlled Trials?*, 340 NEW ENG. J. MED. 804 (1999).

116. *See* Beverly Woodward, *Challenges to Human Subject Protections in US Medical Research*, 282 JAMA 1947, 1948, 1950–52 (1999); *see also* INST. OF MED., RESPONSIBLE RESEARCH: A SYSTEMS APPROACH TO PROTECTING RESEARCH PARTICIPANTS 6 (Daniel D. Federman et al. eds., 2003) ("The protection of research participants is fundamental and should remain paramount to any research endeavor."); Michael Baram, *Making Clinical Trials Safer for Human Subjects*, 27 AM. J.L. & MED. 253, 282 (2001) ("[W]e have drifted away from traditional regard for safeguarding humans in the process of testing and advancing a new technology . . . . [N]o outcomes justify degrading the process to the point where humans are viewed as expendable resources."); Goldner, *supra* note 73, at 125 ("It may well be the case that the effect of providing such information would be that the patient may refuse to

After recognizing that the boundary between quality improvement and research has "great practical importance" under federal regulations,[117] Pearson et al. proceeded under the mistaken assumption that those regulations only prohibit coercive research. "To be sure, patients seeking access to the new technology covered by insurance only under CED have an *inducement* to participate in research; however, this is no different than seeking access to an experimental treatment only available in clinical trials."[118] Because the federal regulations require that researchers "minimize the *possibility* of coercion *or undue influence*,"[119] the authors' implicit second claim (namely, that the undoubted possibility of influence does not rise to the level of "undue") requires more careful consideration.

Although HHS did not elaborate on what it meant by the phrase "undue influence," it had borrowed this language from the well-known Belmont Report,[120] which offered the following further explanation: undue influence may occur "through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance," adding that "inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable."[121] The HHS regulations add that consent forms must include "[a] statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject

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participate . . . , choosing instead to be treated with the preferred treatment method off-protocol. This, however, is not an unreasonable price to pay for respecting the individual's autonomy.").

117. *See* Pearson et al., *supra* note 70, at 989 ("If a data-gathering process is considered research, federal regulations require that a variety of procedures must be followed to protect the participants involved.").

118. *Id.* (emphasis added).

119. 45 C.F.R. § 46.116 (2009) (emphasis added); *see also id.* § 46.101(a)(1) ("Research that is conducted or supported by a federal department or agency . . . must comply with all sections of this policy."); Goldner, *supra* note 73, at 128 ("[I]t has been understood that the possibility of coercion or undue influence is a major concern in the solicitation of subjects to participate in research protocols.").

120. *See* Protection of Human Subjects; Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral, 44 Fed. Reg. 23,192 (Apr. 18, 1979).

121. *Id.* at 23,195; *see also id.* at 23,197 (explaining that vulnerable subjects "are easy to manipulate as a result of their illness or socioeconomic condition"); *id.* at 23,195 ("[I]t is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include . . . threatening to withdraw health services to which an individual would otherwise be entitled."); COUNCIL FOR INT'L ORGS. OF MED. SCI., INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (2002), http://www.cioms.ch/frame_guidelines_nov_2002.htm ("Intimidation in any form invalidates informed consent.").

may discontinue participation at any time."[122] Thus, the federal rules do not concern themselves only with the use of threats to secure the consent of research subjects.

At least one commentator has argued that offering to pay for an item or service only if a patient enrolls in a clinical trial would violate these federal regulations:

> A decision to participate in medical research cannot be truly voluntary, however, when participation is the only way to receive the service. This is particularly troublesome in light of the fact that the particular intervention has likely already been FDA-approved as safe and effective, deemed appropriate for the patient by the patient's treating physician, and considered by CMS to be sufficiently reasonable and necessary to be approved for Medicare beneficiaries, but only so long as they agree to participate in research.[123]

As noted earlier, Pearson et al. responded that such inducements in no way differ from other RCTs.[124] Indeed, even if patients have access to therapeutic substitutes, lack of insurance coverage and limited personal resources may prompt them to enroll in clinical trials as the only hope for accessing medical care.[125] If offers of free access to treatment never create the possibility of undue influence, then only excessive bonus payments

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122. 45 C.F.R. § 46.116(a)(8); *see also* Emanuel et al., *supra* note 67, at 2707 ("[R]espect includes permitting subjects to change their mind . . . and to withdraw without penalty."); Goldner, *supra* note 73, at 128 ("A long-standing principle of informed consent to research mandates an absolute right of a subject both to refuse to participate in research and to withdraw from it once involvement has commenced.").

123. Carnahan, *supra* note 22, at 264–65 ("CMS may be engaging in coercion or undue influence in violation of federal regulations in the sense that coverage of the service is essentially the patient's reward for enrolling in the trial.").

124. *See supra* note 94 and accompanying text; *see also* Allen L. Gifford et al., *Participation in Research and Access to Experimental Treatments by HIV-Infected Patients*, 346 NEW ENG. J. MED. 1373, 1373, 1376 (2002); Sarah Hewlett, *Consent to Clinical Research—Adequately Voluntary or Substantially Influenced?*, 22 J. MED. ETHICS 232 (1996).

125. *See* Gina Kolata & Kurt Eichenwald, *For the Uninsured, Drug Trials Are Health Care*, N.Y. TIMES, June 22, 1999, at A1; *see also* Christine Grady, *Vulnerability in Research: Individuals with Limited Financial and/or Social Resources*, 37 J.L. MED. & ETHICS 19 (2009). Situational vulnerability (to coercion rather than deception) explains the general prohibition on research with prisoners to guard against the possibility that subjects would enroll in the hope of securing early release or other favorable treatment. *See* 45 C.F.R. § 46.302 (2009) (recognizing that "prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research"); Rachel Wener, Comment, *Not Situated to Exercise Free Power of Choice: Human Subject Research in Prison Settings*, 26 TEMP. J. SCI. TECH. & ENVTL. L. 365, 379–83 (2007); *see also* Sydney P. Freedberg, *Questions Raised over AIDS Research on Inmates*, ST. PETE. TIMES, Mar. 19, 2000, at 1A; Mike Ward & Bill Bishop, *Becoming Guinea Pigs to Avoid Poor Prison Care: Ill Inmates Urge Each Other to Join Experiments*, AUSTIN AM.-STATESMAN, Dec. 17, 2001, at A1.

would raise any concerns.[126] One of Pearson's co-authors previously had argued forcefully against even this view, however, suggesting that payment for research participation ethically differs in no way from wages offered to employees, including compensation for jobs that may pose risks.[127]

Pearson et al. rely heavily on a variant of the argument that the greater power (here to deny coverage altogether) includes the lesser power (here to offer coverage subject to conditions).[128] In other contexts, this type of legal reasoning has fared poorly. For instance, the "unconstitutional conditions" doctrine asks whether the government inappropriately demands that an individual forego exercising a constitutionally protected right in order to secure access to a benefit. It represents a reaction to the now generally

126. *See generally* Neal Dickert & Christine Grady, *What's the Price of a Research Subject? Approaches to Payment for Research Participation*, 341 NEW ENG. J. MED. 198 (1999); Christine Grady, *Money for Research Participation: Does It Jeopardize Informed Consent?*, AM. J. BIOETHICS, Spr. 2001, at 40; Carl Elliott, *Guinea-Pigging*, NEW YORKER, Jan. 7, 2008, at 36.

127. *See* Ezekiel J. Emanuel, *Ending Concerns About Undue Inducement*, 32 J.L. MED. & ETHICS 100 *passim* (2004). Emanuel went so far as to suggest that undue inducement would never occur in clinical trials. *See id.* at 104 ("We need to stop talking about undue inducement in clinical research."); *id.* at 102 ("Because independent review of clinical research excludes trials exposing participants to excessive discomforts and risks, undue inducement plays no role in clinical research."); *see also id.* at 100 ("[C]laims of undue inducement . . . should be treated with skepticism, placing a heavy burden of proof on those advancing such charges."). This conclusion depends on a remarkably anemic definition of the concept (and without any evident attention paid to the surrounding language in the regulation much less the fact that the cited rule actually used the somewhat broader term "influence" rather than "inducement"). *See id.* at 101 ("Absent potentially serious adverse consequences of the bad judgment there is no undue inducement. . . . These characteristics differentiate undue inducement from coercion and exploitation, with which it is frequently conflated." (footnote omitted)); *see also id.* at 103 ("The charge of undue inducement may be surreptitious paternalism by risk-averse individuals over decisions properly left to autonomous individuals."). It also seemingly ignores the emphasis on ensuring voluntariness, reducing "informed consent" to a simple question of adequate disclosure. *See id.* at 103 (discussing concerns that high inducements might lead to poor comprehension). Volitional impairment in a domain where we want only genuine volunteers to participate fundamentally distinguishes medical research from the employment setting that Emanuel chooses as his ethical benchmark. *Cf. id.* at 102 ("How can it be reasonable to invite people to enroll in a particular trial for no money, but unreasonable—even unethical—to invite them to enroll in the same trial for $100, $1,000, or even $10,000?"). For a different set of responses to Emanuel's position, see Joan McGregor, *"Undue Inducement[*"*] as Coercive Offers*, AM. J. BIOETHICS, Sept.–Oct. 2005, at 24.

128. Their subsequently published article did so explicitly. *See* Miller & Pearson, *supra* note 70, at 748 ("[O]ffers of benefit may come legitimately with strings attached—that is, with conditions that one would not choose apart from the desire to receive the offered benefit."); *id.* ("For example, government institutions may offer to pay medical tuition in exchange for a specified period of family practice in a rural community or medical service in the military."). The CSP policy does not, of course, offer a simple monetary bonus to beneficiaries who volunteer to participate.

discredited distinction between rights and privileges,[129] and the often associated premise that the government's greater power not to bestow a privilege at all includes the lesser power to provide that privilege conditionally.[130]

At its base, the unconstitutional conditions doctrine attempts to identify situations where the government has impermissibly pressured a beneficiary to relinquish a constitutional right. Narrowly conceived, coercion exists only if a person is put to a choice involving an unlawful option,[131] but coercion arguably also exists where a choice leaves the person worse off than they were previously.[132] In the typical unconstitutional conditions challenge, however, the government has offered to make a person better off in a tangible sense than they were previously, and it does not force them to accept a benefit conditioned on the waiver of rights. Instead, the doctrine recognizes that, even without coercion, persons often face seriously constrained choices and that the government's offer may encourage waivers of their rights without valid consent. "Exploitation" (or "manipulation") may be more apt a term than coercion.[133]

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129. *See* William W. Van Alstyne, *The Demise of the Right-Privilege Distinction in Constitutional Law*, 81 HARV. L. REV. 1439, 1442 (1968); *cf.* Rodney A. Smolla, *The Reemergence of the Right-Privilege Distinction in Constitutional Law: The Price of Protesting Too Much*, 35 STAN. L. REV. 69, 69 (1982) ("[T]he doctrine has shown an uncanny ability to reconstitute itself in spite of the best efforts of scholars and jurists to bury it.").

130. *See* Brooks R. Fudenberg, *Unconstitutional Conditions and Greater Powers: A Separability Approach*, 43 UCLA L. REV. 371, 519 (1995) (concluding that, although the greater-includes-the-lesser argument makes some sense, heightened judicial scrutiny is appropriate in those cases where a lesser power is separated from the greater power along a constitutionally protected dimension); John H. Garvey, *The Powers and the Duties of Government*, 26 SAN DIEGO L. REV. 209, 215–19 (1989) (discussing the limitations of this argument); Michael Herz, *Justice Byron White and the Argument That the Greater Includes the Lesser*, 1994 BYU L. REV. 227, 238–49 (same).

131. *See supra* Part II.B; *see also* WERTHEIMER, *supra* note 91, at 202–21; Daniel Lyons, *Welcome Threats and Coercive Offers*, 50 PHIL. 425, 436 (1975); Jeffrie G. Murphy, *Consent, Coercion, and Hard Choices*, 67 VA. L. REV. 79, 83 (1981) (responding to "the mistaken assimilation of all hard decisions made under pressure of grim alternatives to cases of duress or coercion").

132. *See* Robert Nozick, *Coercion*, *in* PHILOSOPHY, SCIENCE, AND METHOD 440, 447 (Sidney Morgenbesser et al. eds., 1969) (arguing that coercion exists when threatened action would make one worse off than they "would have been in the normal or natural or expected course of events"); *see also* Peter Westen, *"Freedom" and "Coercion"—Virtue Words and Vice Words*, 1985 DUKE L.J. 541, 558–93; David Zimmerman, *Coercive Wage Offers*, 10 PHIL. & PUB. AFF. 121, 124–38 (1981); *cf.* James Lindgren, *Unraveling the Paradox of Blackmail*, 84 COLUM. L. REV. 670, 701–04 (1984) (explaining that blackmail is treated as coercion even though the threatened act—disclosure of damaging but truthful information about the victim—is not considered unlawful).

133. *See, e.g.*, FADEN & BEAUCHAMP, *supra* note 65, at 258–60, 354–62; JOEL FEINBERG, HARM TO SELF 242–49 (1986) (explaining that exploitation exists where one party takes advantage of another's weakness or dependency); *see also* WERTHEIMER, *supra* note 92, at

Because of its wildly inconsistent application by the Supreme Court, the unconstitutional conditions doctrine has attracted its fair share of scholarly attention. A number of competing formulations have been suggested by commentators,[134] including one that attempts to distinguish "threats" from "offers" by reference to some baseline,[135] or one that identifies situations where the government appears to be exercising monopoly power,[136] but the Supreme Court has not explicitly embraced any of these approaches.[137] Whether or not a Medicare beneficiary successfully could assail the CSP policy as an unconstitutional condition,[138] the doctrine offers instructive

123–57 (calling unconstitutional conditions a form of exploitation); *cf.* Richard R.W. Fields, Comment, *Perks for Prisoners Who Pray: Using the Coercion Test to Decide Establishment Clause Challenges to Faith-Based Prison Units*, 2005 U. CHI. LEGAL F. 541, 558–67.

134. *See* Kathleen M. Sullivan, *Unconstitutional Conditions*, 102 HARV. L. REV. 1413 (1989) (canvassing several competing theories based on notions of coercion, corruption, and commodification, and offering instead a "systemic" theory calling for strict scrutiny of rights-pressuring conditions on government benefits because they skew the distribution of power between and among the government and governed). "[U]nconstitutional conditions doctrine responds to a constant fear that government will tend to use the strategic manipulation of gratuitous benefits to aggrandize public power." *Id.* at 1493.

135. *See* Seth F. Kreimer, *Allocational Sanctions: The Problem of Negative Rights in a Positive State*, 132 U. PA. L. REV. 1293, 1352 (1984) ("[T]he distinction between liberty-expanding offers and liberty-reducing threats turns on the establishment of an acceptable baseline against which to measure a person's position after imposition of an allocation."). Kreimer proposed that history, equality, and prediction serve as relevant baselines. *See id.* at 1359–74; *see also* Kenneth W. Simons, *Offers, Threats, and Unconstitutional Conditions*, 26 SAN DIEGO L. REV. 289, 311–17 & n.78 (1989) (rejecting history and equality in favor of a modified predictive baseline).

136. *See* Richard A. Epstein, *The Supreme Court, 1987 Term—Foreword: Unconstitutional Conditions, State Power, and the Limits of Consent*, 102 HARV. L. REV. 4, 102 (1988) (concluding that "the traditional norms prohibiting coercion and duress are insufficient to police the legal monopoly that government exercises over certain critical domains"); *see also* RICHARD A. EPSTEIN, BARGAINING WITH THE STATE 312 (1993) (concluding that "a government that has any level of monopoly power cannot be trusted to impose whatever conditions it wants").

137. *See* Lynn A. Baker, *The Prices of Rights: Toward a Positive Theory of Unconstitutional Conditions*, 75 CORNELL L. REV. 1185, 1195 (1990) (noting that all commentators concede that "the Court has yet to arrive, explicitly or implicitly, at a clear limiting principle for deciding challenges to conditions on government benefits"); Cass R. Sunstein, *Is There an Unconstitutional Conditions Doctrine?*, 26 SAN DIEGO L. REV. 337, 338 (1989) ("Whether a condition is permissible is a function of the particular constitutional provision at issue; on that score, anything so general as an unconstitutional conditions doctrine is likely to be quite unhelpful."). For recent reviews of this subject, see Mitchell N. Berman, *Coercion Without Baselines: Unconstitutional Conditions in Three Dimensions*, 90 GEO. L.J. 1 (2001); Daniel A. Farber, *Another View of the Quagmire: Unconstitutional Conditions and Contract Theory*, 33 FLA. ST. U. L. REV. 913 (2006).

138. *Cf.* Mem. Hosp. v. Maricopa County, 415 U.S. 250 (1974) (holding that a state cannot deny access to medical care because an otherwise eligible person had exercised a fundamental right to travel); Heather S. Dixon, *Pelvic Exam Prerequisite to Hormonal Contraceptives: Unjustified Infringement on Constitutional Rights, Governmental Coercion, and Bad Public*

insights for the ethical debate: semantic quibbles should not distract from efforts to judge the acceptability of conditions on public health insurance coverage that would obligate patients to "volunteer" for research, and the various indignities that come with it,[139] in order to secure access to a needed item or service.

D. Undervaluing Autonomy: Communitarian Research Ethics

Perhaps the most stunning and potentially radical justification for CSP appears in the final paragraph of the *JAMA* article by Pearson et al. when they invoked society's "interest in greater knowledge" as a relevant factor "[i]n assessing the ethics of CED."[140] As they elaborated: "Patients who share in the benefits of society, and who ask for society to pay for these benefits, arguably should share a willingness to contribute to the body of evidence that will improve the quality and value of the health care of tomorrow."[141] In our autonomy-based tradition of bioethics,[142] such an

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Policy, 27 HARV. WOMEN'S L.J. 177, 209–17 (2004) (arguing that publicly funded family planning clinics cannot condition access to oral contraceptives on intrusive exams that serve only collateral purposes); *id.* at 231–32 (concluding that, while physicians should discuss risks and separately might encourage a pelvic exam, women retain the right to make an informed choice to use oral contraceptives without first undergoing such an exam); Andrew Zoltan, Comment, Jacobson *Revisited: Mandatory Polio Vaccination as an Unconstitutional Condition*, 13 GEO. MASON L. REV. 735 (2005) (arguing that, once an infectious disease such as smallpox has been eradicated, mandatory immunizations no longer serve a public health purpose and, if made a prerequisite for access to public education, would violate the unconstitutional conditions doctrine). *But cf.* Lars Noah, *Too High a Price for Some Drugs?: The FDA Burdens Reproductive Choice*, 44 SAN DIEGO L. REV. 231, 253 (2007) ("What if the government demanded contraceptive use as a condition of Medicaid reimbursement for drugs that create a risk of birth defects?"); *id.* at 254 (concluding that this "looks more like a nonsubsidy than a penalty because a woman receiving public assistance for drug coverage would remain free (in theory) to refuse contraception and pay for the [teratogenic] drug out of pocket").

139. *See supra* note 73. Individuals enjoy rights of bodily integrity that would allow them to decline unwanted medical interventions unless the state had some powerful justification. *See* Washington v. Glucksberg, 521 U.S. 702, 720, 724–25 (1997); *In re* Cincinnati Radiation Litig., 874 F. Supp. 796, 810–14 (S.D. Ohio 1995) (situating a subject's right to bodily integrity in substantive due process); *see also* Ken Marcus Gatter, *Protecting Patient-Doctor Discourse: Informed Consent and Deliberative Autonomy*, 78 OR. L. REV. 941, 961–82 (1999).

140. Pearson et al., *supra* note 70, at 990.

141. *Id.* Medicare beneficiaries who had made substantial contributions through separate payroll taxes would quibble with any suggestion that the program represents nothing more than government largesse, just as taxpayers who have underwritten NIH and other publicly-funded biomedical research would take issue with insinuations that they have callously free-rided on the unselfish efforts of others. *Cf.* Claude Lenfant, *Clinical Research to Clinical Practice—Lost in Translation?*, 349 NEW ENG. J. MED. 868, 868 (2003) (noting that NIH had received more than $250 billion in appropriations since 1950).

142. *See* Carl E. Schneider, *Bioethics with a Human Face*, 69 IND. L.J. 1075, 1085 (1994) (calling autonomy "the centerpiece of bioethics"). Other countries do not share our perhaps excessive preoccupation with autonomy. *See* George J. Annas & Frances H. Miller, *The*

invocation of the "greater good" would set off alarm bells.[143] It suggests a distinctly public health approach to resolving questions about human subjects protection,[144] which may make perfect sense for the types of outcomes research envisioned by the CAD policy but becomes far more troubling when extended to RCTs under the CSP policy. Indeed, if persuaded by this notion of a quid pro quo, then why not insist that all Medicare (and Medicaid) beneficiaries sign up for at least one RCT, whether or not they want access to a novel and expensive intervention?

A few commentators have offered suggestions that nicely illustrate where such an approach might take us. One scholar recently floated the idea of compulsory research service.[145] Although it has become increasingly

Empire of Death: How Culture and Economics Affect Informed Consent in the U.S., the U.K., and Japan, 20 AM. J.L. & MED. 357, 377 (1994); *id*. at 373–75 (focusing on Japan).

143. During the two decades after World War II, and notwithstanding issuance of the Nuremberg Code, biomedical researchers in this country acted quite freely—utilitarianism prevailed over the more protective norms that only emerged in the late 1960s after revelations of domestic research abuses. *See* DAVID J. ROTHMAN, STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISION MAKING 51 (2d ed. 2003) ("Utilitarian justifications that had flourished under conditions of combat and conscription persisted, and principles of consent and voluntary participation were often disregarded."); *see also id*. at 37 (explaining that malaria experiments conducted by the U.S. military on prisoners were lauded at the time as promoting the war effort).

144. *See* Scott Burris et al., *Applying the Common Rule to Public Health Agencies: Questions and Tentative Answers About a Separate Regulatory Regime*, 31 J.L. MED. & ETHICS 638, 643–46 (2003) (contrasting the ethical issues that arise in biomedical research and public health investigation); *id*. at 645 ("If in Common Rule practice autonomy is a trump, or at every fork directs research and practice activity down the more autonomy-enhancing path regardless of other considerations, then there is a tension with public health."); *id*. at 638 ("A nascent public health ethics movement has articulated ethical approaches that differ with those that generated the Common Rule."); Daniel Callahan & Bruce Jennings, *Ethics and Public Health: Forging a Strong Relationship*, 92 AM. J. PUB. HEALTH 169, 170 (2002) (referring to "the predominant orientation in favor of civil liberties and individual autonomy that one finds in bioethics, as opposed to the utilitarian, paternalistic, and communitarian orientation that have marked the field of public health throughout its history"); Nancy E. Kass, *An Ethics Framework for Public Health*, 91 AM. J. PUB. HEALTH 1776, 1777–78 (2001).

145. *See* Rosamond Rhodes, *In Defense of the Duty to Participate in Biomedical Research*, 8 AM. J. BIOETHICS 37 (2008). For a range of responses to her idea, see Robert J. Levine, Editorial, *Reflections on 'Rethinking Research Ethics*,*'* 5 AM. J. BIOETHICS 1 (2005) (introducing a symposium devoted to the topic). For earlier and generally milder versions of this proposal, see Arthur L. Caplan, *Is There a Duty to Serve as a Subject in Biomedical Research?*, IRB: REV. OF HUM. SUBJECTS RES., Sept.–Oct. 1984, at 1, 4–5; Goldner, *supra* note 73, at 124–25 (noting that "the argument has been made that, at least with respect to research involving only minimal risk, there is an ethical obligation of citizens to participate in such research"); John Harris, *Scientific Research Is a Moral Duty*, 31 J. MED. ETHICS 242 (2005). For further debate on this idea, see Iain Brassington, *John Harris' Argument for a Duty to Research*, 21 BIOETHICS 160 (2007); Sarah Chan & John Harris, *Free Riders and Pious Sons—Why Science Research Remains Obligatory*, 23 BIOETHICS 161 (2009).

difficult to recruit sufficient numbers of subjects for trials,[146] conscripting people for this purpose would represent a radical solution that likely no one would take seriously.[147] In the summer of 2009, a high-level NIH official made an urgent plea seeking more than two thousand adults willing to participate in clinical trials of experimental vaccines against the novel H1N1 ("swine") flu virus.[148] Given widespread fears about that emerging pandemic, researchers had little difficulty recruiting enough subjects; if, however, an insufficient number of people volunteered, public health agencies clearly would not—and should not—have the power to draft citizens into service as unwilling guinea pigs simply because this would serve the greater good.

David Orentlicher offered a more cautious variant of the conscription proposal. In response to the difficulties caused by underenrollment in RCTs, he would allow physicians to condition continued care on their patients' willingness to enroll in trials comparing established therapies.[149] Orentlicher conceded that such a recruitment strategy would raise objections about coercion,[150] but he emphasized that patients have no right

146. *See supra* note 1.

147. *See* Richard Delgado & Helen Leskovac, *Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice*, 34 UCLA L. REV. 67, 120 n.228 (1986) ("[S]ociety has not yet decided that human subjects may be conscripted (like soldiers) without their consent."); *id.* at 94 ("When the research subject does not choose freely to participate, his act loses its moral meaning. Participation in the research is not something given by the subject; rather, it is something extracted."); Epstein, *supra* note 100, at 569 ("We are no longer worried about the prospect that individuals will be conscripted into medical trials against their will."); Hans Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, 98 DAEDALUS 219, 234–35 (1969); Mortimer B. Lipsett, *On the Nature and Ethics of Phase I Oncology Trials of Cancer Chemotherapies*, 248 JAMA 941, 942 (1982) (distinguishing research participation from military conscription); Robert M. Veatch, *Which Grounds for Overriding Autonomy Are Legitimate?*, HASTINGS CTR. REP., Nov.–Dec. 1996, at 43 (warning that subjugating autonomy whenever it might promote the common good "would justify conscripting people into dangerous research against the will of subjects if the social benefits were great enough"). The bioethicists at NIH evidently would dismiss such objections as reflecting a bygone era. *See* Ezekiel J. Emanuel & Christine Grady, *Four Paradigms of Clinical Research and Research Oversight*, 16 CAMBRIDGE Q. HEALTHCARE ETHICS 82 (2007) (arguing that a communitarian-based paradigm has partially displaced the protectionist approach that prevailed in the 1970s and 1980s); *infra* note 155 and accompanying text (discussing a civic obligation to participate in research recently proposed by Emanuel and a couple of his other colleagues at NIH's Department of Bioethics).

148. *See* Donald G. McNeil, Jr., *Clinical Trials for Flu Vaccine Are to Begin Soon*, N.Y. TIMES, July 23, 2009, at A4.

149. *See* David Orentlicher, *Making Research a Requirement of Treatment: Why We Should Sometimes Let Doctors Pressure Patients to Participate in Research*, HASTINGS CTR. REP., Sept.–Oct. 2005, at 20, 21–22, 27. Pediatric oncologists routinely do something along these lines with experimental interventions. *See id.* at 23; Gina Kolata & Kurt Eichenwald, *In Pediatrics, a Lesson in Making Use of Experimental Procedures*, N.Y. TIMES, Oct. 3, 1999, § 1, at 40.

150. *See* Orentlicher, *supra* note 149, at 21, 23. Even the bioethicists at NIH apparently

to continuous treatment from a particular physician.[151] In that case, however, his proposed limitation to comparative efficacy trials seems unduly narrow.[152]

Orentlicher viewed his proposal as less extreme than Medicare's CSP policy,[153] but he also conceded that, in all likelihood, it would fail to comply with our existing—and, to his mind, overly protective—research subject protections.[154] If, however, Pearson et al. offered a persuasive defense of CSP, then Orentlicher's idea would not require any alteration in those ethical safeguards, and the still more radical conscription proposals would not seem as outlandish as most commentators seem to think. As it happens, in July 2009, a group of NIH bioethicists published a piece in *JAMA* arguing that all citizens have a civic—though not (yet) compulsory—obligation to participate in biomedical research.[155] Their provocative

would object. *See* Hawkins & Emanuel, *supra* note 92, at 19 ("[I]f a physician-researcher threatened to abandon a patient or withhold necessary standard treatment unless the patient joined a study, this would clearly be coercion.").

151. *See* Orentlicher, *supra* note 149, at 25–26; *cf. id.* at 22 (conceding that the termination of an existing doctor-patient relationship for a refusal to enroll might look more like a "penalty").

152. He thought that the minimal risks associated with comparative efficacy trials made his proposal more acceptable, *see id.* at 24–25, thereby suggesting that he harbored some lingering concerns about its potentially coercive nature. In addition, though he praised the societal value of such research, *see id.* at 21, Orentlicher resisted the temptation to rest his ethical defense of the proposal on utilitarian grounds, *see id.* at 24.

153. *See id.* at 22 (calling his proposal "more cautious" because "the CMS policy affects research on tests or treatments whose efficacy has not been established for the patients being studied").

154. *See id.* ("Under current practice, it is highly unlikely that [IRB] approval would be given to a study in which physicians made participation in the study a condition for receiving treatment."); *id.* at 22–23 (quoting directly relevant language from the Declaration of Helsinki); *see also id.* at 20 ("question[ing] whether research safeguards are sometimes overly protective"); *id.* at 27 (concluding that, in some cases, "ethical safeguards can become too strict").

155. *See* G. Owen Schaefer et al., *The Obligation to Participate in Biomedical Research*, 302 JAMA 67, 67–71 (2009) (rejecting the arguments offered by other proponents of this idea based on beneficence and free-riding, instead basing the obligation on the view that generalizable medical knowledge amounts to a public good for which all members of society should contribute their fair share); *id.* at 69 (drawing an analogy to expectations that academics occasionally agree to comment on manuscripts for peer-reviewed journals); *id.* (adding that it would resemble civic obligations such as voting rather than compulsory duties); *id.* (recognizing as legitimate excuses religious convictions, excessive burdensomeness, and significant risks, and emphasizing that informed consent would remain necessary); *id.* at 70 ("[E]ncouragement would have to be given carefully; there is a risk that the patients would fear abandonment by their physician if they refused to participate."); *see also id.* at 67 (disclosing their purpose "to stimulate support for a major cultural shift in the way physicians, researchers, patients, and society at large think about participation in research"); *id.* at 70 ("One strategy to affirm and reinforce the belief that individuals have an obligation to participate in research would be a publicity campaign analogous to get-out-the-

article represents a natural extension of the justifications that they previously had offered in defense of the CSP policy, and it comes perilously close to endorsing outright conscription.[156]

CONCLUSION

CMS has discovered a creative way to use its leverage over beneficiaries in order to generate useful information. It has done so in a manner that has more in common with the Pentagon's often heavy-handed approach to the use of investigational drugs than with the FDA's more subtle and indirect methods for encouraging the production of biomedical knowledge. The CSP policy appears to run afoul of federal research regulations, which only represent ethical minima in any event. Indeed, the agency's effort to skirt those regulations and justify its ethically dubious initiative rather than to steer well clear of existing restrictions itself sets a poor example for the broader research community.

During the last decade, NIH has attracted an impressive group of bioethicists who have produced a remarkable body of scholarly work. The legacy of their efforts will come to rival even the most influential reports produced in the past by federal commissions charged with providing the government with ethical guidance. Unlike members of these commissions, however, the bioethicists employed by NIH serve a client, and some of their published work defending federal initiatives bears a troubling resemblance to that produced by their professional counterparts in legal departments serving other agencies. Advocacy pieces produced by these bioethicists—serving as apologists for the work of their institutional employers—should draw sustained attention and, if necessary, serious rebuttals from independent scholars. Otherwise, the current bioethical party line could lead us down a worrisome path in society's relentless pursuit of biomedical advance.

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vote efforts, which have helped convince 90% of US citizens that there is a duty to vote.").

156. *See id.* at 70 ("The situation is in some ways analogous to a wartime call to arms in which . . . soldiers to fight are needed."); *id.* at 71 ("[J]oining the army is more risky and time-consuming than any clinical trial that has been approved by a well-functioning institutional review board."); *see also* Schuck, *supra* note 65, at 924 ("The autonomy principle is deeply entrenched in our culture and law; few exceptions to it—compulsory immunization and military conscription are the major examples—have been recognized." (footnotes omitted)); *cf.* LARS NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY 176 (2d ed. 2007) ("Should participation in biomedical research be viewed as a civic duty akin to serving on a jury?!"); C.D. Herrera, *Universal Compulsory Service in Medical Research*, 24 THEORETICAL MED. 215, 223–25 (2003) (imagining a system that resembles jury duty).