

sparse, so why should clinicians and researchers need to adhere to more stringent consent standards when providing those same therapies in a research context?

Clinical research is designed to narrow the scope of clinical uncertainty by identifying unknown risks and benefits and determining which therapy is most effective. Inviting patients (who are already in a vulnerable state) into this realm of uncertainty — no matter how small — without fully acknowledging the implications of their participation is to treat them as passive instruments of medical expertise rather than as people who deserve to exercise control over their lives. That such invitations may take place in the clinical setting without this acknowledgment is not an argument for easing research consent requirements — it is an argument in favor of strengthening clinical consent standards.

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No potential conflict of interest relevant to this letter was reported.

1. Reith C, Landray M, Devereaux PJ, et al. Randomized clinical trials — removing unnecessary obstacles. *N Engl J Med* 2013; 369:1061-5.

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THE AUTHORS REPLY: The consent process should appropriately inform clinical-trial participants of relevant aspects of the trial, including the reasonably foreseeable risks and alternative available treatments (with their potential benefits and

risks).¹ In the context of trials comparing widely accepted treatments, the alternative to participation in the trial is essentially the receipt of routine clinical care. Robust safety and efficacy data to support the use of many treatments commonly used in practice is lacking, yet such treatments are frequently prescribed without discussing this uncertainty with the patient, and hence by extension they are effectively prescribed without informed consent. For example, aspirin is commonly prescribed as primary prevention for patients with diabetes who do not have vascular disease, despite a paucity of reliable knowledge about the risks or benefits of this approach. If trial procedures remain disproportionate to their likely hazards as compared with routine medical care, medical practice will continue to use therapies unknowingly that may be damaging because of the impediments to conducting trials to resolve such uncertainties. These evidence gaps are harmful to individual patients and public health.

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Since publication of their article, the authors report no further potential conflict of interest.

1. International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use. Guideline for good clinical practice E6(R1). June 10, 1996 (http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1_Guideline.pdf).

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Abusive Prescribing of Controlled Substances

TO THE EDITOR: In their Perspective article, Betset and Brennan (Sept. 12 issue)¹ state that overdose of a controlled substance has become the second-leading cause of accidental death in the United States. They go on to discuss the ethical duty of pharmacists to combat this growing public health problem. To this end, they report on the effort undertaken by their employer, CVS Caremark, to curtail the inappropriate prescribing of narcotics.

However, the senior vice president and chief

medical officer of CVS Caremark neglect to mention that in April 2013, their company paid \$11 million in fines to settle charges brought by the Drug Enforcement Administration that CVS pharmacies in Oklahoma and elsewhere were violating the Controlled Substances Act by irresponsibly dispensing narcotics.²

All the while, CVS has continued to sell the nation's leading avoidable cause of death — tobacco³ — in nearly every 1 of its 7400 drug stores nationwide. Pharmacists and physicians

alike have long decried the practice of cigarette sales in pharmacies.^{4,5} Retailers of tobacco products should no longer be granted licenses to dispense medications or to provide health care services.

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Dr. Jha reports having founded TobaccofreeRx, a nonprofit organization dedicated to ending tobacco sales in pharmacies. Dr. Blum reports chairing the board of advisors of TobaccofreeRx. No other potential conflict of interest relevant to this letter was reported.

1. Bettes M, Brennan T. Abusive prescribing of controlled substances — a pharmacy view. *N Engl J Med* 2013;369:989-91.
2. CVS to pay \$11 million to settle civil penalty claims involving violations of Controlled Substances Act. Press release of the United States Drug Enforcement Agency, April 3, 2013 (<http://www.justice.gov/dea/divisions/hq/2013/hq040313.shtml>).
3. The health consequences of smoking: a report of the Surgeon General. Atlanta: Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2004.
4. Richards JW, Blum A. Pharmacists who dispense cigarettes: with reference to drug store chains and pharmaceutical companies. *New York State J Med* 1985;85:350-3.
5. Hudmon KS, Fenlon CM, Corelli RL, Prokhorov AV, Schroeder SA. Tobacco sales in pharmacies: time to quit. *Tob Control* 2006; 15:35-8.

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The following meetings will be held: "MultiSpecialty Fellowship Summit 2013" (Orlando, FL, Dec. 14 and 15); "Asian-American MultiSpecialty Summit VI: Laparoscopy & Minimally Invasive Surgery" (Honolulu, Feb. 12–15); and "Minimally Invasive Surgery Week 2014: Annual Meeting and Endo Expo" (Las Vegas, Sept. 10–13).

Contact the Society of Laparoendoscopic Surgeons, 7330 SW 62nd Place, Suite 410, Miami, FL 33143; or call (305) 665-9959; or fax (305) 667-4123; or see <http://www.sls.org>.

CLEVELAND CLINIC FLORIDA

The following meetings will be held: "Cleveland Clinic Multispecialty Pathology Symposium: A Practical Diagnostic Approach to Surgical Pathology & Cytology" (Weston, FL, Feb. 1 and 2); "25th Anniversary Jagelman/35th Anniversary Turnbull International Colorectal Disease Symposium 2014" (Fort Lauderdale, FL, Feb. 11–16); and "3rd Annual Gastroenterology and Hepatology Symposium" (Fort Lauderdale, FL, Feb. 13–15).

Contact Cleveland Clinic Florida, 2950 Cleveland Clinic Blvd., Weston, Florida 33331; or call (954) 659-5490; or fax (954) 659-5491; or e-mail cme@ccf.org; or see <http://www.clevelandclinicfloridacme.org>.

BAPTIST HEALTH SOUTH FLORIDA

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Contact Baptist Health South Florida, CME Department, 8900 N. Kendall Drive, Miami, FL 33176; or call (786) 596-2398; or e-mail cme@baptisthealth.net.

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