permitting patents on new crystalline structures, formulations, and single-isomer isolations of mixed enantiomer products, even though many of these alterations to existing molecules would be obvious to skilled chemists and offer no therapeutic novelty. This determination does not require an assessment of clinical superiority.

A low nonobvious threshold increases prices because pharmaceutical manufacturers can claim exclusivity over, extensively market, and charge more for products that have patent-protected minor changes than for the older products they replace, which are often on the cusp of generic competition. In 2011, Congress created a streamlined administrative process for reexamining patents (inter partes review) that is helping to address some of these issues. Additional progress could be achieved by mandating review of pharmaceutical patents when they are registered with the US Food and Drug Administration (FDA), with a government or public interest lawyer tasked with challenging the patent's validity.[1] The solution for problems caused by understaffing of the Patent and Trademark Office is obvious.

Second, Arbiser inappropriately downplays the role that scientists outside the United States have played in innovation, particularly transformative drug development. One review of research productivity from 1982 through 2003 found greater output per dollar invested in Europe than the United States.[2] There is no evidence that drug registration costs in the United States are substantially higher than elsewhere or that the United States requires more data for drug approvals than other countries; experience over the last decade shows that the FDA is the fastest drug regulatory agency in the world.[3] Although drug development is unarguably expensive, the 24% profit margin forecast for brand-name drug manufacturers in 2016 is again among the highest of all global industries,[4] suggesting there is room to advance affordability and access for US patients and preserve robust incentives for private investment in innovation. The claim that companies' costs in commercializing a drug "dwarf" the costs of achieving the (often publicly funded) discoveries on which the drug is based is unsubstantiated and almost certainly incorrect.

We agree with Mr Roy and colleagues that corporate governance structures and other financial pressures affect corporate behavior. High annual growth targets can also contribute to companies heavily marketing their products for off-label uses in violation of FDA rules, with the hope that gains in profits will far exceed any fines.[5] Though many off-label uses are not evidence-based and can pose substantial risks to patients, this practice is likely to grow with the protection of off-label promotion under the First Amendment, leading to increased spending on prescription drugs without clear accompanying patient benefit.[6] The data Roy and colleagues present on the enormous sums spent by drug makers merely to buy back their own shares, thus increasing their market price, makes a telling point about the misdirection of the industry's enormous profits toward goals other than research and development.

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Expectations for Physicians Prescribing Marijuana

To the Editor The Viewpoint on medical board expectations for physicians recommending marijuana[1] summarized model guidelines proposed by the Federation of State Medical Boards (FSMB) for its members.[2]

We have 2 principal concerns. Regarding conflicts of interest, Dr Chaudhry and colleagues stated, "the physician should not be associated in any way with a dispensary or cultivation center." This wording is more restrictive than the actual policy ratified by the FSMB. It would impede physicians who wish to collaborate with dispensaries and cultivators in studying which specific cannabinoid:terpenoid ratios patients find effective. Such data collection, in the absence of desperately needed clinical trials, can help unravel the diverse efficacy of various cannabinoids. Such an association for research purposes should not exclude physicians who recommend medicinal cannabis.

Also worrisome is the recommendation by Chaudhry and colleagues that "state medical and osteopathic boards advise their licensees to abstain from the use of marijuana for medical or recreational purposes while actively engaged in the practice of medicine." This provision does not appear in the model guidelines developed by the FSMB Workgroup, adopted as policy by the FSMB House of Delegates in April 2016.[2]

Although most physicians enter rehabilitation programs because of dependence on alcohol, opioids, or both, the FSMB does not advise that users of recreational alcohol or prescribed opiates suspend their practice. Using medicinal cannabis is not prima facie evidence of impairment or abuse. Advising those physicians to suspend practice would be an unwarranted intrusion into a private physician-patient relationship and a stigmatization of clinicians making a rational

treatment decision, in consultation with their physicians, about a substance with a lower addiction potential than either alcohol or opiates. The proposed policy to disallow such usage is scientifically unsupportable.

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1. Chaudhry HJ, Hengerer AS, Snyder GB. Medical board expectations for physicians recommending marijuana. *JAMA*. 2016;316(6):577-578.

2. Federation of State Medical Boards. Model guidelines for the recommendation of marijuana in patient care. http://www.fsmb.org/Media/Default/PDF/BRD_RPT_16-2_Marijuana_Model_Guidelines.pdf. Accessed September 21, 2016.

In Reply In response to Dr Hergenrather and colleagues, the FSMB model guidelines do not prohibit and are not meant to impede physician association with dispensaries for research purposes. The policy states: "A physician who recommends marijuana should not have a professional office located at a dispensary or cultivation center or receive financial compensation from or hold a financial interest in a dispensary or cultivation center. Nor should the physician be a director, officer, member, incorporator, agent, employee, or retailer of a dispensary or cultivation center." Our Viewpoint was not intended as a substitute for the model guidelines, but as a general summary. Physicians should refer directly to the guidelines for formal guidance.[1]

The FSMB's Workgroup on Marijuana and Medical Regulation, which drafted the model policy, did not believe a statement regarding physicians' use of marijuana should be included in its report, opting in favor of a separate and distinct policy statement[2] as the appropriate vehicle to communicate to physicians, on behalf of boards, that engaging in the practice of medicine while under the influence of marijuana, for medical or recreational purposes, would be considered unprofessional conduct. In April 2016, the FSMB House of Delegates unanimously adopted both the model policy and the policy statement. Marijuana was also added to the list of substances that impair ability in the FSMB's model policy, "Essentials of a State Medical and Osteopathic Practice Act," section IX, entitled "Disciplinary Action against Licensees."[3]

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1. Federation of State Medical Boards. Model guidelines for the recommendation of marijuana in patient care. https://www.fsmb.org/Media/Default/PDF/BRD_RPT_16-2_Marijuana_Model_Guidelines.pdf. Accessed September 30, 2016.

2. Federation of State Medical Boards. Resolution 16-3: physicians' use of marijuana. https://www.fsmb.org/Media/Default/PDF/Advocacy/FSMB%20Resolution1.pdf Accessed September 30, 2016.

3. Federation of State Medical Boards. Essentials of a State Medical and Osteopathic Practice Act: section IX: disciplinary action against licensees: subsection D-19. http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/GRPOL_essentials.pdf Accessed September 30, 2016.

CORRECTION

Label Error in Figure: In the Research Letter entitled "Temporal Changes in the Association Between Modifiable Risk Factors and Coronary Heart Disease Incidence," published in the November 15, 2016, issue of *JAMA*,[1] the first line of numbers under the Figure should be "Prevalence by each risk factor (range), %." The numbers represent prevalence of each risk factor depicted above (systolic blood pressure, diabetes, smoking, lipids) and not prevalence of coronary heart disease in these groups. This article was corrected online.

1. Navar AM, Peterson ED, Wojdyla D, et al. Temporal changes in the association between modifiable risk factors and coronary heart disease incidence. *JAMA*. 2016;316(19):2041-2043.

Guidelines for Letters

Letters discussing a recent *JAMA* article should be submitted within 4 weeks of the article's publication in print. Letters received after 4 weeks will rarely be considered. Letters should not exceed 400 words of text and 5 references and may have no more than 3 authors. Letters reporting original research should not exceed 600 words of text and 6 references and may have no more than 7 authors. They may include up to 2 tables or figures but online supplementary material is not allowed. All letters should include a word count. Letters must not duplicate other material published or submitted for publication. Letters not meeting these specifications are generally not considered. Letters being considered for publication ordinarily will be sent to the authors of the *JAMA* article, who will be given the opportunity to reply. Letters will be published at the discretion of the editors and are subject to abridgement and editing. Further instructions can be found at http://jamanetwork.com/journals/jama/pages/instructions-for-authors. A signed statement for authorship criteria and responsibility, financial disclosure, copyright transfer, and acknowledgment and the ICMJE Form for Disclosure of Potential Conflicts of Interest are required before publication. Letters should be submitted via the *JAMA* online submission and review system at http://manuscripts.jama.com. For technical assistance, please contact jama-letters@jamanetwork.org.

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