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"Focus on childhood fitness, not just fatness."

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In summary, the establishment of a single UK medical research fund should be supported as long as the research requirements of patients, clinicians, and the NHS are given appropriate priority and performance is properly audited. Annual funding of laboratory-based research by UK charities and the MRC is already close to £1·0 billion, which dwarfs the project funding spent on practice-oriented clinical research. Whilst it is imperative that high-quality basic science is not undermined, we have been unwise in the past to put quite so many of our eggs in the laboratory basket. Elucidation of the basic biology of health and disease is vital, but experience shows that therapeutic spin-offs cannot be taken for granted and that we must therefore invest similar resources in practice-oriented research to improve routine diagnosis, prognostication, existing therapies, palliation, and prevention of disease, which are generally much lower-hanging fruit anyway, and enhance clinical innovation, which has been so extraordinarily productive in the past. Cooksey should therefore ensure that the ex-NHS R&D budget is spent on the types of truly "clinical" research for which it was originally intended.

Peter M Rothwell
Stroke Prevention Research Unit, University of Oxford, Radcliffe Infirmary, Oxford OX2 6HE, UK
peter.rothwell@clneuro.ox.ac.uk

I previously held an MRC Senior Clinical Fellowship and have ongoing MRC funding. I have academic interests in both clinical and translational research. I declare that I have no other conflict of interest.

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FDA regulation of tobacco: reprieve for the Marlboro man?

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In 2000, the US Supreme Court threw out regulations[1] on tobacco advertising and cigarette sales to minors imposed in 1996 by former Food and Drug Administration (FDA) Commissioner David Kessler.[2] Since then, the Campaign for Tobacco-Free Kids has led an effort to lobby for the passage of federal legislation that would put all tobacco products under a single regulatory roof.[3]

If enacted, the Family Smoking Prevention and Tobacco Control Act (currently pending in Senate and House Committees) would give the Food and Drugs Administration (FDA) regulatory authority over tobacco products and would be the first federal legislation on tobacco since the 1988 airline-smoking ban.

Is Congress on the verge of standing up to Big Tobacco? Maybe not, when one of the most vocal champions of this bill turns out to be none other than the nation's largest cigarette company. Philip Morris, maker of Marlboro, the top cigarette brand in the USA and throughout the world, now marches shoulder-to-shoulder with the Campaign for Tobacco-Free Kids, the American Cancer Society, and the American Heart Association, among others, in lobbying for passage of the legislation[4–6] (all of the other major tobacco companies oppose the bill).

In a statement issued upon re-introduction of the FDA tobacco legislation in both the House and Senate, Altria Group, Inc (Philip Morris' parent company) stated: "Altria and PM [Philip Morris] USA strongly support the passage of this legislation and remain committed in our support for comprehensive, meaningful and effective FDA regulation of tobacco products."[4]

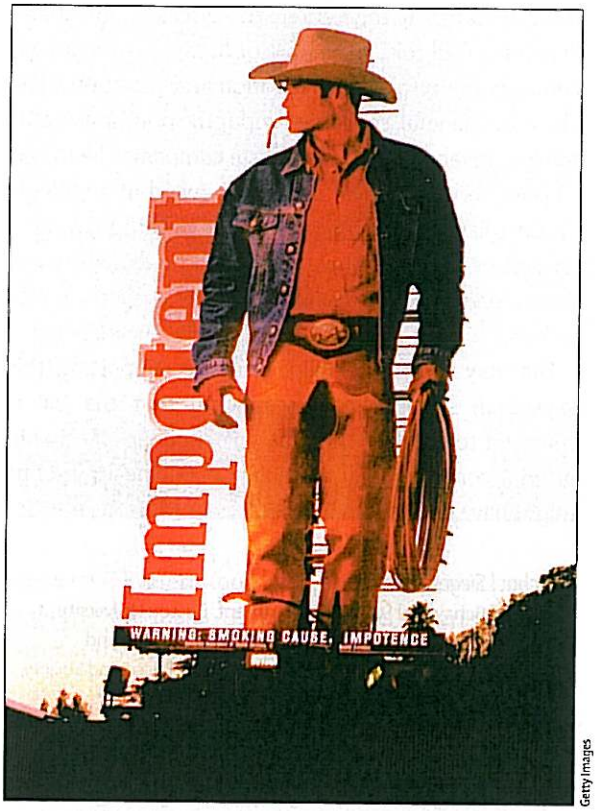
Philip Morris' support for the bill should prompt scepticism about the legislation's public-health benefits. Reading the fine print bears this out. Consider the following. First, the measure would stringently regulate new and potentially less hazardous tobacco products, but would not apply these same regulatory standards to the most irredeemably harmful form of tobacco, existing cigarettes, which cause the deaths of nearly half a million Americans each year.

Second, although the bill would require the FDA to prevent the introduction of new cigarette brands for which "there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health,"[7] the bill permits Marlboro and the other most popular existing cigarette brands to remain on the market, even though these products are one of the leading threats to the public's health.

Third, the bill bans the use of strawberry, grape, chocolate, or similar flavouring additives in cigarettes but does not require the FDA to eliminate (or even reduce the levels of) toxic gases, including hydrogen cyanide or the more than 40 known cancer-causing constituents of cigarette smoke such as benz(a)pyrene, benzene, and radioactive polonium. The Agency would be given the authority to take such action but, unlike for the flavourings, there is no mandate that the FDA do anything to regulate these toxins.

Although the bill stringently regulates new cigarette products, existing products will be subject to performance standards that would allow the FDA to require reduction or elimination of certain constituents in the tobacco smoke.[7] However, it is not known which of the many chemicals in cigarette smoke, at what levels, and in what combination, are responsible for the observed pulmonary, cardiovascular, and carcinogenic effects of tobacco products.

Furthermore, even if the FDA were to take action, the bill reserves to Congress the right to ban any class of tobacco products. The bill also reserves to Congress the right to



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reduce nicotine levels to zero. This loophole precludes the FDA itself from assisting in making cigarettes non-addictive by virtue of severe reductions in nicotine levels. Most importantly, the bill provides Congress with specific veto power over the FDA's actions.[7]

History has shown that the tobacco industry has outwitted public-health advocates at every attempt to impose federal tobacco legislation. The main goal of the Federal Cigarette Advertising and Labeling Act of 1970[8] was to remove ubiquitous cigarette ads from the broadcast media. Yet no sooner had overt cigarette commercials left the airwaves than televised sports events, such as the Marlboro Grand Prix, the Virginia Slims Tennis Circuit, and Winston Cup Racing, began proliferating.[9,10]

Tobacco companies have also outmanoeuvred health advocates who believed they had found a way to use the industry's money to fund antismoking education. The Master Settlement Agreement of 1998 has resulted in a tiny fraction of settlement funding being directed toward smoking prevention and cessation programmes.[11] Only four states are currently allocating to tobacco prevention the minimum amount

recommended by the Centers for Disease Control and Prevention; all told, only 2·6% of tobacco revenues are being spent on tobacco prevention and cessation.[11] The attorneys general, concerned about the potential loss of tobacco revenues should cigarette companies be forced to post bond to appeal a punitive award in an Illinois product liability lawsuit, as required by state law, filed an amicus brief[12] to prevent the bond payment which they argued would have diverted funds away from state coffers.[12]

The very fact that Philip Morris is supporting this legislation should create scepticism that the bill is sufficient to diminish the tobacco pandemic and should prompt concern that, once again, public-health groups might have been outsmarted.

Michael Siegel, Alan Blum
Social and Behavioral Sciences Department, Boston University School of Public Health, Boston, MA 02118, USA (MS); and University of Alabama Center for the Study of Tobacco and Society, Tuscaloosa, Alabama, USA (AB)
mbsiegel@bu.edu

We declare that we have no conflict of interest.

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Government tobacco regulation: opportunity for change

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Cigarettes remain largely free from safety standards, meaningful testing, or regulation in most of the world, decades after the Royal College of Physicians and the US Surgeon General concluded that cigarette smoking causes lung cancer and other serious diseases. The adoption of the Framework Convention on Tobacco Control (FCTC) that requires each ratifying country to implement legislation "for the testing and measuring as well as the regulation of the contents and the emissions of tobacco products" provides a unique opportunity to correct this gap. However, its potential will be realised only if public-health authorities learn from the past, resist the temptation to adopt solutions that do not lead to fundamental change, and prevent the debate from being dominated by extreme views that lead to inaction.

The need to capitalise on the opportunity provided by the FCTC is urgent. WHO Assistant Director-General, Catherine Le Galès-Camus declared on May 30, 2006, World No Tobacco Day: "Regulating all forms of tobacco products cannot be delayed. It is vital to any effective tobacco control programme, and a must if we are to control this epidemic."[1]

The tobacco industry has long taken advantage of the absence of regulation to hide the truth about the health effects of their products;[2] create a marketplace dominated by products such as Marlboro and Camel; deceive consumers about so-called reduced risk products;[3] and engage in marketing that is deceptive,[4] appealing to youth, and encourages continued tobacco use.[5,6]

The experience with low-tar cigarettes shows the harm that comes from the absence of meaningful regulation.