YANKEE DOODLING **Douglas Kamerow**

NIH updates its conflict of interest guidelines

How much does the public need to know about reports of conflicts?

Last week the US National Institutes of Health (NIH) published its long awaited final rule on conflicts of interest (http://1.usa.gov/rstfft).[1 2] In doing so it tried to balance the benefits of increased disclosure of financial connections between NIH funded investigators and the industry with the drawbacks of a greater burden of reporting and loss of privacy.

This issue came to broad public attention about three years ago, when a series of investigations by Senator Charles Grassley uncovered several highly publicised scandals. A few NIH funded scientists were found to have huge undisclosed investments in drugs they were testing or to have received large "consulting" fees that had not been reported to their universities.[3] They were disciplined.

Financial relationships between academia and industry have grown dramatically in recent years. A widely publicised 2009 report on conflicts of interest from the Institute of Medicine documented that growth.[4] More than two thirds of academic departments and most department chairs have financial relationships with the industry, such as consulting, board memberships, and intellectual property licensing. Companies now commonly fund research centres or programmes and, in some cases, entire departments. Industry funding of biomedical research has almost tripled in the 10 years since the current conflict of interest rules were introduced in 1995, to $94.3bn (£58bn; €65bn).[5]

As I noted when it was released,[6] the 2009 Institute of Medicine report included a broad set of recommendations about all facets of conflicts of interest—not just financial—in biomedical research, medical education, creation of clinical practice guidelines, medical practice, and medical institutions. The recommended actions targeted everyone from medical students to deans and included drug and device companies, the NIH, practising doctors, medical societies, and the US Congress as well. The final NIH conflict of interest rule is much narrower, focusing on scientists' financial conflicts and their reporting.

Under a headline titled "HHS [Department of Health and Human Services] tightens financial conflict of interest rules for researchers," NIH's press release accompanying the new rule[7] focused on the following changes:

- Decreased thresholds for reporting, to $5000 from $10 000
- Required disclosures of financial interests by investigators and leaders of institutions, relating to their research and to their institutional responsibilities
- Required management of conflicts by institutions, with required reporting to the funding agency, and
- Required training for investigators in conflict of interest policies and regulations.

In an accompanying statement NIH's director, Francis Collins, said, "Strengthening key provisions of the regulations with added transparency will send a clear message that NIH is committed to promoting objectivity in the research it funds."

But a government watchdog group, headed by a former investigator for Senator Grassley, wasted no time in lambasting the new rule.[8] Asking how and what exactly will be disclosed about the conflicts, the Project on Government Oversight pointed to what had been deleted from the draft version of the report released for public comment last year. Apparently the draft report required posting on the internet of conflicts of interest by institutions, a requirement that was dropped from the final version. The final rule requires that investigators and others report their financial interests and that the institutions "manage" them and report all this to the funder. The public is never informed unless there is a request for the information, presumably through some sort of freedom of information query.

"Some institutions had objected that maintaining a website of all the reported conflicts would have been an expensive undertaking. That seems hard to believe. Websites are not expensive to mount today"

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Also, it seems that the new rule does not go beyond requiring the institutions to "manage" the potential conflicts, without defining exactly what that means. One of the strengths of the 2009 Institute of Medicine report was its insistence that mere disclosure was not enough of a remedy for competing interests. It recommended eliminating conflicts wherever possible, by removing or sharply limiting participation by investigators in conflicted research projects. That was a very radical suggestion, one that NIH was certainly not prepared to take on.

One explanation for the scaled back requirements in the final rule was that President Barack Obama asked government agencies to try to decrease the burden of all the regulations they issue. The final rule includes a detailed estimate of the fiscal burden on institutions of complying with the new policies. Some institutions objected that maintaining a website of all the reported conflicts would have been an expensive undertaking.

That seems hard to believe. Websites are not expensive to mount today. Even a brief look at university and hospital websites makes it hard to argue that devoting a few pages to lists of reported conflicts would be a huge burden, especially as the conflicts need to be reported anyway.

As NIH's Dr Collins said, transparency is a good goal; but it would have been better if the NIH had required public reporting and had created guidance for what is permitted and what is not. The fact that senior leaders in an institution know who is getting paid large consulting fees and who has stock in what company does not necessarily mean that the public can have faith that undue influence has been prevented.

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References are on bmj.com

LOBBY WATCH **Richard Cookson**

Media Smart

What is it?

Almost two thirds of UK primary schools will receive free teaching aids from Media Smart by the end of 2011 (http://bit.ly/omPspF). The non-profit media literacy programme provides reading and writing material that focuses on advertising.

Media Smart says that its teaching packs, which it says are created by educational experts and cover topics such as language, images, and production across commercial media, "teach children to think critically about advertising in the context of their daily lives" (http://bit.ly/naYUEH).

But parents might view the lessons that their children are learning differently if they knew that the programme was funded by some of the world's most powerful toy and fast food companies. The supporters are the Advertising Association, the British Toy and Hobby Association, Business in the Community, DDB London, Ferrero, Five, GMTV, Hasbro, the Internet Advertising Bureau, the Incorporated Society of British Advertisers, ITV, Jetix, Lego, Mars, Mattel, McDonald's, MediaCom, Mindshare, Turner, and Viacom (http://bit.ly/nRcVSy).

The teaching packs for 6 to 11 year olds have included advertisements for food products and fast food retailers. Media Smart says that teachers might use the materials in various ways, such as projects for the end of term or by picking activities to suit lesson plans.

When Media Smart was launched in 2002 the *Financial Times* said that the initiative showed "the seriousness with which the industry is now viewing a potential ban on marketing to children" (http://bit.ly/mOxKpB).

What agenda does it have?

The Children's Food Campaign of Sustain, an umbrella organisation for groups campaigning for better food and farming, has called Media Smart's approach "particularly reprehensible," because its lesson plans repeatedly involve viewing advertisements for junk food.

The campaign says, "Teachers are instructed to show adverts for Burger King, Frosties, Pepsi, McDonalds, Walkers Crisps and the sugary cereal Hunny Bs." The programme is funded by McDonald's, Kelloggs, Mars, Ferrero, and other food manufacturers (http://bit.ly/qISmfC).

Christine Blower, general secretary of the National Union of Teachers, warned: "While there is nothing wrong with companies genuinely seeking to use their resources to support schools on a philanthropic basis, it seems that manufacturers of fast foods can't help but introduce their support accompanied by subliminal, and not so subliminal, advertising. Teachers should look with caution at what is on offer."

The Children's Food Campaign says that changes in advertising regulations since 2007 mean that it would not be possible to broadcast an advertisement for Hunny Bs now, as the use of licensed characters to market food to children is now restricted. Showing it to children in a classroom, however, remains legal (http://bit.ly/qISmfC).

Media Smart counters critics by saying that it uses hundreds of real life examples of advertising in its materials. It defends its past use of the Hunny Bs advertisement, saying that the materials were written before the new advertising rules were proposed in September 2007 (Charlotte Higgo, Media Smart, personal communication, 5 October 2010).

Where does it get its money from?

Although Media Smart acknowledges that it is supported by the UK advertising business, its website does not make entirely explicit its link to an advertising industry lobby group called the World Federation of Advertisers, which champions and defends the interests of advertising companies.

The federation represents around 90% of global marketing communications worth almost $700bn (£430bn; €490bn) a year (http://bit.ly/rtpZ01). It has lobbied against proposals by the European Union and the World Health Organization for tighter restrictions on marketing of food to children (http://bit.ly/pAySN7; http://bit.ly/nAv7pu).

Media Smart's chairman is Paul Jackson, also regional vice president of the World Federation of Advertisers (http://bit.ly/qr6Fjb). The federation says that it "wholeheartedly supports" Media Smart but does not "fund Media Smart and has no formal links to the programme" (Will Gilroy, World Federation of Advertisers, personal communication, 13 December 2010).

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BMJ.COM BLOGS

Richard Vize on banning outdoor smoking

Four years after the ban on smoking in public buildings was extended across the UK, libertarian hackles are being raised again, this time by local government moves to ban it outdoors.

The localism bill includes a "power of general competence" allowing councils to act in the interests of their communities, unless that action is prevented by other law. A few councils are examining whether they could use this power to extend the smoking ban to playgrounds, parks, sports venues, and even streets.

BEN CAWTHRA/REX

In England the first battleground in the new hostilities over smoking has been the historic town of Stony Stratford—"we offer free parking and five star loos"—in Buckinghamshire. Town councillor Paul Bartlett has been branded a fresh air fascist in the *Daily Telegraph* for calling for a ban on smoking in public places, including the high street. A "mass light up" outside the town council meeting bore hazy witness to local opposition. So many people tried to cram themselves into the hall that proceedings had to be adjourned to the local church. As the vicar pleaded from the pulpit for the multitude to moderate their unecclesiastical language, Bartlett failed to attract a single supporter.

But elsewhere there has been more success for voluntary bans aimed at protecting children. Councils such as Hackney, Pendle in Lancashire, and parts of Wiltshire have put up "no smoking" signs in children's playgrounds. They aren't legally enforceable, but are making it increasingly unacceptable to smoke near children.

Voluntary bans seem to be the best approach. Indeed, until it is tested in the courts it is unclear whether the localism bill really does give councils the power to impose more restrictions.

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REALITY CHECK **Ray Moynihan**

Is your mum on drugs?

When "de-prescribing" may be the best medicine

Soon after she went into a small hospital a few years back, Johanna Trimble's mother in law seemed to enter a rapid physical and cognitive decline.

Fervid Trimble was at the time a woman in her late 80s, living independently in a senior citizens' home near Seattle in the United States. After a bout of diarrhoea and dizziness she was admitted to the healthcare centre close to the home, but her family was soon shocked by the quick deterioration in her health and the emergence of some strange new symptoms, including delusions. "She wasn't able to wake up, and we couldn't wake her," says Johanna. "It didn't seem like normal sleep."

After discussions with the centre's staff the family discovered that Fervid was taking several new drugs, including a painkiller and an antidepressant. "They said she was depressed," says Johanna, "but we believed that she was rightly grieving for the loss of her former life, because she was now stuck inside a hospital room. It made sense to us that she was sad."

At the same time a psychiatrist diagnosed "Alzheimer's" and suggested that the 88 year old take donepezil (Aricept), which the family declined after learning that there was little evidence that the drug offered clinically meaningful benefits.

After further research the family members began to suspect that their mother was overmedicated and experiencing the harmful effects of a drug interaction, rather than depression or Alzheimer's disease. In consultation with health centre staff they opted for a partial "drug holiday," winding back some of Fervid's treatments.

"She recovered completely," Johanna told the *BMJ* last month. "Not only cognitively, but she was also soon doing exercises again. She really came right back." The family members have compelling before and after photos to back up their views, which are part of a presentation that Johanna now regularly delivers, called "Is your mom on drugs?" (http://bit.ly/pcfBhw).[1]

As a journalist who's been writing about evidence for many years, I'm acutely aware of the benefits and risks of the powerful anecdote. Used inappropriately, anecdotes can and do distort understanding and mislead readers—a daily reality of the hype based reporting in tabloids and on screens around the world.

In this case, though, hearing what happened to Fervid Trimble helps tell the wider story of the dangerous overdrugging of our elders and the fact that families and loved ones can do something to stop it.

The first thing Fervid's family did was to tell the doctors that she was not to be given any new drugs without the family's permission, and they've since released a short set of tips urging people to listen closely to their older loved ones, compare any new "symptoms" with drug side effects, and seek out independent, reliable evidence.[2]

For Johanna Trimble the experience was life changing. "I was looking at all the other people in long term care facilities, where family members were either unaware of the problems or didn't want to rock the boat, and I thought, 'Who the hell is going to speak up for these people?'" she told the *BMJ*. She has since become a patients' advocate, working with public agencies and communities in Canada where she lives, promoting the idea that discontinuing drugs can sometimes be the best prescription. "I really wanted to do something about this epidemic of overmedication of our elders."

Last year the *Archives of Internal Medicine* published a feasibility study of drug discontinuation among elderly people in Israel,[3] with extraordinary findings. Using an established tool, researchers were able to cut the average number of medications in half, from roughly eight to fewer than four per person. Just 2% of discontinued drugs were restarted; no adverse effects of discontinuation were reported; and almost 90% of people reported better health.

"She was admitted to the healthcare centre close to the home, but her family was soon shocked by the quick deterioration in her health and the emergence of some strange new symptoms, including delusions"

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The study was co-run by Dee Mangin, an academic at Christchurch School of Medicine in New Zealand and a general practitioner who is well schooled in evidence about the harms of unnecessary care. "I look as hard at stopping medications for my patients as I do at starting them," she says.

Dr Mangin has written previously in the *BMJ* about the way that quality measures can drive up prescriptions of questionable benefit and why the current approach to "preventive care" for elderly people requires a rethink.[4] "Improving the art of 'not doing' is what will determine quality care in the next few decades," argues Dr Mangin, who is part of an informal global network hoping to run a randomised controlled trial of "de-prescribing."

For Johanna Trimble, reducing numbers of unnecessary drugs and the associated delirium didn't just improve her mother in law's health; a returned lucidity in the following years of her life also enabled Fervid to pass on the precious wisdom of those facing death.

"Before she died, she spoke to all of us, touching and inspiring us, pouring out all her wisdom and love," says Trimble. "Many families are not having these powerful experiences because their elders are too drugged." Perhaps as northern hemisphere health professionals return from well earned holidays, the idea of a drug holiday for their elderly patients might be something to mull over.

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