REALITY CHECK **Ray Moynihan**

Too much medicine, not enough mirth

It is 10 years since a *BMJ* special theme issue in 2002 posed the question "Too much medicine?"

If there's to be a global campaign to wind back overmedicalisation and iatrogenic illness, surely the best strategies include comedy and satire. The latest outbreak of satirical sanity comes from the US television comedian Stephen Colbert, who recently promoted the idea of "meducation," a plan to use attention-deficit/hyperactivity disorder (ADHD) drugs to lift the school performance of healthy children.

Reinforcing the truism that truth is stranger than fiction, Colbert's skit was inspired by actual comments reported the day before. "I don't have a whole lot of choice," a paediatrician, Michael Anderson, told the *New York Times*, explaining why he prescribed amphetamines to healthy kids. "We've decided as a society that it's too expensive to modify the kid's environment. So we have to modify the kid."[1]

While childbirth, menopause, and ageing are strong contenders, ADHD is arguably now the best known example of overmedicalisation. A recent study of almost a million Canadian children found that boys with birthdays in the school entry cut-off month of December—and thus the youngest in the classroom—were a third more likely than boys born in January to be given a diagnosis of the condition and to be treated.[2]

Ten years ago the *BMJ* published a theme issue called "Too Much Medicine?" which I guest edited with the then editor, Richard Smith.[3 4] ADHD got a mention, along with sexuality, genetic medicalisation, and the downsides of screening. "The biggest risk for the population right now," wrote Peter Gøtzsche of the Nordic Cochrane Centre, "may be the uncritical adoption of screening tests for cancer."[5] His evidence based sentiment has become ever more salient a decade later, particularly in relation to screening for prostate and breast cancer.

Overselling medicine? The *BMJ* special theme issue of 13 April 2002

Biomedical psychiatry was also singled out in "Too Much Medicine?" as a potentially dangerous source of medical imperialism—concerns with echoes today in the critical backlash against the ever expanding *Diagnostic and Statistical Manual of Mental Disorders*, the DSM. One of the funniest takes on medicalising normality of the mind comes from satirists at the *Onion* magazine. For anyone who hasn't seen its slick television news item about the first ever approved "depressant" drug, this really is a medical must see, already viewed by 1.7 million.[6] The new drug "Despondex" has been approved for people classified as "annoyingly cheerful"; symptoms include "squealing loudly" and "excessive hugging."

Less viewed, but equally recommended, is the mock marketing campaign for the new drug Havidol, "when more is not enough." The work of the artist Justine Cooper, the Havidol campaign has appeared as an art exhibition, a beautifully designed website (havidol.com), and an exquisite advertisement. In keeping with the best "direct to consumer" marketing, the Havidol advertisement features a young actor in a pool explaining that, like millions of women, she was sometimes "worried about life," concerned about her weight, had noticed the "signs of aging," and felt stressed. The scientific explanation was that brain chemistry was being compromised by busy lives, leaving sufferers feeling "less than best." The good news was that Havidol could help, as long as it was taken "indefinitely"—though do watch out for the side effects.

"The new drug 'Despondex' has been approved for people classified as 'annoyingly cheerful'; symptoms include 'squealing loudly' and 'excessive hugging'"

None of this humour is aimed at de-legitimising or re-stigmatising genuine illness. Rather, it's blowing the cultural whistle on the disease mongering that characterises so much of what passes as mainstream medicine, gnawing away at our self confidence, as Lynn Payer powerfully put it in her book *Disease-Mongers*.[7] The resources wasted in treating pseudo-disease can be much better spent preventing and treating legitimate illness. It seems, however, that concern may now be giving way to concerted action. As reported this month in the *BMJ*, various organisations around the world are starting to imagine a new global coalition to tackle overmedicalisation, overdiagnosis, and overtreatment.[8]

Among the many obstacles to such a movement will, of course, be motivational deficiency disorder, estimated in 2006 to affect one in five.[9] Later this year a new prevalence survey will be rolled out globally, using a recently validated five item questionnaire. It asks:

1) Have you ever felt lazy?
2) Do you have a family history of laziness?
3) Do you ever feel somnolent while reading medical journal articles?
4) Have you ever considered hiring someone to clean the gutters on your roof?
5) Are you breathing?

If you answered yes to any of these questions, you should definitely see your doctor.

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Ray Moynihan is undertaking a PhD and helping organise with the *BMJ* an international conference on overdiagnosis, to be held at the Dartmouth Institute for Health Policy and Clinical Practice, New Hampshire, on 10-12 September 2013 (see www.preventingoverdiagnosis.net). References are in the version on bmj.com.

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bmj.com

Previous articles by Ray Moynihan are available at http://bit.ly/Rp92TV

BMJ OPEN DATA CAMPAIGN **Fiona Godlee**

Open letter to Roche about oseltamivir data

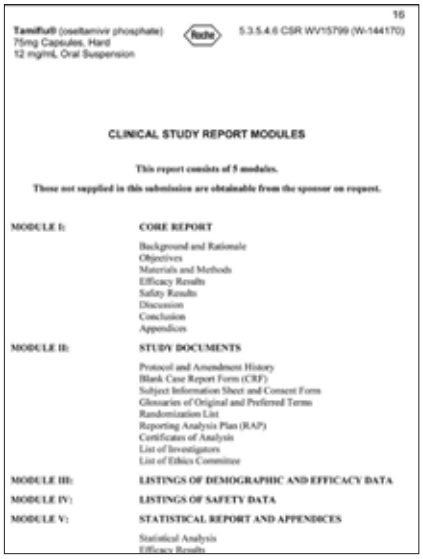
Roche promised in 2009 to release full data from trials of oseltamivir after a *BMJ* and Cochrane Collaboration investigation. In a letter to John Bell, regius professor of medicine at Oxford University and a Roche board member, the *BMJ*'s editor in chief further urges Roche to disclose the full data

Dear John

I am writing to you in your capacity as a member of the board of Roche. As you may be aware, the *BMJ* has been working with the Cochrane Collaboration in its efforts to get Roche to release the raw data on the effects of oseltamivir (Tamiflu) so that Cochrane can properly fulfil the UK government's commission for a systematic review of neuraminidase inhibitors based on clinical study reports.

To remind you of the background to this, in 2009 the *BMJ* published the updated Cochrane review of neuraminidase inhibitors in healthy adults.[1] This took the view that, since eight of the 10 randomised controlled trials on which effectiveness claims were based were never published and because the only two that had been published were funded by Roche and authored by Roche employees and external experts paid by Roche, the evidence could not be relied on. The *BMJ* also published an article summarising the Cochrane team's efforts to obtain the data from these randomised controlled trials and a feature investigation exploring the underlying issues.[2 3]

After these articles were published, we and the Cochrane Collaboration received public assurances from Roche that the data from these 10 trials would be made available to physicians and scientists.[4] Although some further data have been released to the Cochrane reviewers, the data that were promised ("full study reports") have not been made available.


Tamiflu® (oseltamivir phosphate) 75mg Capsules, Hard 12 mg/mL Oral Suspension

Roche

5.3.5.4.6 CSR WV15799 (W-144170)

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CLINICAL STUDY REPORT MODULES

This report consists of 5 modules.

Those not supplied in this submission are obtainable from the sponsor on request.

MODULE I: CORE REPORT

Background and Rationale
Objectives
Materials and Methods
Efficacy Results
Safety Results
Discussion
Conclusions
Appendices

MODULE II: STUDY DOCUMENTS

Protocol and Amendment History
Blank Case Report Form (CRF)
Subject Information Sheet and Consent Form
Glossaries of Original and Preferred Terms
Randomization List
Reporting Analysis Plan (RAP)
Certificates of Analysis
List of Investigators
List of Ethics Committee

MODULE III: LISTINGS OF DEMOGRAPHIC AND EFFICACY DATA

MODULE IV: LISTINGS OF SAFETY DATA

MODULE V: STATISTICAL REPORT AND APPENDICES

Statistical Analysis
Efficacy Results

Example of content of each of the five modules of a full study report

Below is a table showing which "modules" (sections) of the 10 trials Roche has so far refused to make available. Also attached is a graphic, taken from a single study report, which explains the kind of content contained in each module of a full study report. This gives an indication of what can be expected in the modules that Roche has as yet not provided.

The Cochrane reviewers now know that there are at least 123 trials of oseltamivir and that most (60%) of the patient data from Roche's phase III completed treatment trials remain unpublished. We have concerns on a number of fronts: the likely overstating of effectiveness and the apparent under-reporting of potentially serious adverse effects. Meanwhile, oseltamivir has just been added to the World Health Organization's List of Essential Medicines, alongside aspirin and β blockers.

On behalf of the Cochrane collaborators and public health decision makers around the world, I ask Roche to honour its publicly stated promise to make available the full clinical study reports. In order for the Cochrane collaborators to properly analyse these data they will need individual patient data in electronic format.

Oseltamivir has been a great commercial success for Roche. Billions of pounds of public money have been spent on it, and yet the evidence on its effectiveness and safety remains hidden from appropriate and necessary independent scrutiny. I am appealing to you, as an internationally respected scientist and clinician and a leader of clinical research in the United Kingdom, to bring your influence to bear on your colleagues on Roche's board. As company directors, responsibility for Roche's behaviour rests with you, as individuals and collectively. In refusing to release these data of enormous public interest, you put Roche outside the circle of responsible pharmaceutical companies. Releasing the data would do a great deal to restore confidence in the company and its board of directors.

We plan to publish this letter in the *BMJ*, and we would welcome a reply from you to publish alongside it. We would need to receive your reply by Thursday 18 October or Friday 19 at the latest. I look forward to hearing from you.

With best wishes

Yours sincerely

Fiona Godlee

The 10 trials included in the Kaiser et al 2003 review,[5] showing number of modules in the full study report, which modules have been provided to the Cochrane reviewers by Roche to date, and which are being requested

Trial ID	No of patients	Primary publication of trial	Secondary publication of trial	No of modules in full study report	Modules provided by Roche	We are therefore requesting modules
WV15671	629	Treanor et al 2000[6]	Kaiser et al 2003	5	1	2-5
WV15670	726	Nicholson et al 2000[7]	Kaiser et al 2003	5	1	2-5
M76001	1459	Unpublished	Kaiser et al 2003	5	1	2-5
WV15707	27	Unpublished	Kaiser et al 2003	4	1	2-4
WV15730	60	Unpublished	Kaiser et al 2003	4	1	2-4
WV15812, WV15872	404	Unpublished	Kaiser et al 2003	5	1	2-5
WV15876, WV15819, WV15978	741	Unpublished	Kaiser et al 2003	5	1	2-5

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This is an edited version of the letter sent to Roche on 11 October 2012; the original is at bmj.com/tamiflu.

John Bell has responded saying that he has referred the letter to Roche.

References are in the version on bmj.com.

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EDITORIAL, p 7; FEATURE, p 26