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Abstract

“Newspeak,” as Orwellian cognoscenti know, is the official language of Oceania—the land ruled by Big Brother. Newspeak was designed “not to extend but to diminish the range of thought.” Its goal was to “make all other modes of thought impossible.” All of which brings us from the nightmare fantasy of 1984 Newspeak to the health care debate of 2012, the concept of “academic detailing,” and a new term we must all become familiar with—*cost-think* (which defines everything that reduces short-term costs as a benefit to the patient).

Keywords

comparative effectiveness, AHRQ, health care reform, academic detailing

“Newspeak,” as Orwellian cognoscenti know, is the official language of Oceania—the land ruled by Big Brother. Newspeak was designed “not to extend but to *diminish* the range of thought.” Its goal was to “make all other modes of thought impossible.” All of which brings us from the nightmare fantasy of 1984 Newspeak to the health care debate of 2012, the concept of “academic detailing,” and a new term we must all become familiar with—*cost-think* (which defines everything that reduces short-term costs as a benefit to the patient).

According to Dr Jerry Avorn, professor of medicine at Harvard Medical School and chief of the Division of Pharmacoeconomics, “Academic detailing is when healthcare professionals (usually pharmacists) meet with healthcare professionals to provide them with information and educational tools on various treatment options and optimal care, to improve provider knowledge of medical treatment effectiveness, encouraging alignment of practices with established evidence.”¹ Left unsaid, but clearly implicit, is that such detailing is required to offset the free market doings of the pharmaceutical industry. That’s why the more common appellation for academic detailing is *counter detailing*.

Why should anyone care? Well—not to put too fine a point on it—it’s now the law of the land. Significant government funding has been provided to develop and roll out academic detailing programs. Our government is spending tens of millions of tax dollars to tell American physicians how to practice medicine based on comparative effectiveness studies that are commissioned without any public input or transparency. Additionally, the term *academic detailing* isn’t accurate—because the work isn’t being done by academics. It’s government detailing—and the devil is in the details.

- The Agency for Healthcare Research and Quality (AHRQ) hired a firm, Total Therapeutic Management, and is paying it US\$11,680,060 to recruit and train physicians, pharmacists, nurses, and physician assistants.

We need to ask some tough but honest questions: Will physicians be required to be visited by this new battalion of government agents? Will physicians be given incentives to spend time with the Agency for Healthcare Research and Quality’s angels—such as continuing medical education (CME credits)—and punished if they do not (via Medicare and Medicaid restrictions)?

- A US\$4 million “continuing education award” to Prime Education (an educational design and accreditation company focused on continuing medical education programs).

How will the government decide which doctors are to be visited? Will “high prescribers” of on-patent medicines be on a priority list? Barry Patel, the CEO of Total Therapeutic Management, said its top priority is “high volume” practices across 150 metropolitan statistical areas (MSAs) (interview with the author, February 2012). So, rather than focusing on offices with disproportionately high negative patient outcomes, the government is directing its efforts against those doctors who are high prescribers—which is a pretty good indicator about what

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government detailing is all about—decreasing cost rather than improving care.

As Harvard University health economist and health care advisor to President Obama, David Cutler, has noted, “Virtually every study of medical innovation suggests that changes in the nature of medical care over time are clearly worth the cost.”² Access to care must be matched with quality of care. What safeguards are in place to certify that physicians are being presented information that is unbiased? Previous government detailing efforts have often focused on demonstrating their own value by highlighting the cost-effectiveness of initiatives through savings generated from the increased utilization of generics and other low-cost therapies.

When it comes to government detailing (at the taxpayers’ expense), what are the metrics for success? According to Mr Patel, the only metrics are whether or not a physician (1) says the sessions have been useful and (2) asks the detailer to come back to discuss other topics (interview with the author, February 2012). In other words, the metrics are subjective and anecdotal—but not clinical.

There is little information on why so few academic detailing programs attempt to measure overall health care cost reductions or improvement in patient outcomes. This is likely due to the fact that measuring changes in prescription drug costs is a more manageable analysis than determining changes in overall health care spending or clinical results. It also fits into the general cognitive mapping of those who believe that pharmaceutical costs are the main driver of health care costs. In fact, on-patent drug costs represent less than a dime on the American health care dollar.

Interestingly, Mr Patel doesn’t even agree with either the term *academic detailing* or *counter detailing*. “We aren’t counter anything. We’re not there to un-do anything. It’s not good versus bad. . . . Our visits aren’t details . . . they’re the beginning of a process.” And as far as “academic” goes, Mr Patel uses that term because that’s the phrase AHRQ uses and placed in the contract. “Our people are patient-centered outcomes consultants, PCOCs,” says Patel. And his people are largely pharmacists and nurses. A former Merck employee, Patel likens his PCOCs more to pharmaceutical company medical/science liaisons (MSLs) than field representatives. “They’re not discussing product-specific information, but the findings of comparative effectiveness studies. Pharmaceutical companies could do the same thing if they wanted to” (interview with the author, February 2012).

Or could they? This can be argued either way, but in the current environment of regulatory oversight and political “sunshine,” it is unlikely that any pharmaceutical company is going to risk “educating” physicians of comparative effectiveness studies. Nor will they be able to get physicians to grant them a scheduling slot with the promise of CME credits. According to

Patel, when his “outreach experts” phone physicians to request appointments, the fact that the meeting will result in CME credits is always mentioned (interview with the author, February 2012). Would a pharmaceutical company be permitted to offer such an enticement? Would such an offer be “sunshine-able” under state and federal guidelines? And, if so, why don’t government detailers have to share the details of their valued benefactions?

Interestingly, according to the Accreditation Council for Continuing Medical Education (ACCME), government is exonerated from having a commercial interest. (*A commercial interest* is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.) Our nation’s single largest payer, Uncle Sam, is not deemed to have a conflict of interest when it comes to designing and providing physician CME.³

In November 2011, at the International Conference on the Improved Use of Medicines in Antalya, Turkey, Elissa Ladd, a Massachusetts nurse-prescriber, spoke against the detailing practices of Big Pharma toward the growing population of nurse-prescribers. (According to Ms Ladd, there are 150,000 nurse-prescribers in the US, compared with only 100,000 physicians in general practice.) You’ve heard the argument before—pharmaceutical detailing is “bad” because it helps to “sell” products *for profit*! She provided no evidence (anecdotal or otherwise) that the information pharmaceutical detailers provide to nurse-prescribers is in any way slanted or anything other than factual and 100% FDA-compliant.⁴ Yet her organization undertook some “academic detailing” efforts that resulted in nurse-prescribers questioning the reliability of pharma-provided information. She positioned this as “success.”⁴ However, is having nurse-prescribers (or, for that matter, *any* prescriber) discount important vetted and timely medical information really a move in the right direction? That’s more than an academic question.

Reducing the amount of money spent on drugs without improving the quality of care significantly limits the impact of detailing programs on overall health care costs. In fact, it just reinforces the concept of “fail first,” a strategy that’s good for payers—including the government, the nation’s biggest payer—but bad for patient outcomes. A study fielded by the National Consumers League demonstrated that switching patients to less expensive generics doesn’t always result in positive outcomes.⁵

Consider that 15% of general prescription drug users say that they or a family member experienced therapeutic substitution, nearly half were dissatisfied (or their family was) with how the process occurred and report that this substitution did not result in lower out-of-pocket costs, and 40% said that the new medication was not as effective as the original one. What’s

more, nearly a third experienced more side effects following the substitution.⁶

The repercussions of choosing short-term savings over long-term results, of cost-based choices over patient-centric care, of “fail first” policies over the right treatment for the right patient at the right time are pernicious to both the public purse and the public health.

Skimping on a more expensive medicine today but paying for an avoidable hospital stay later is a fool’s errand.

And how can an “academic detailing” program funded by our nation’s largest payer (the government) be considered neutral? Just like detailing programs run by pharmaceutical companies, there is an inherent “interest.” Which is OK as long as that “interest” is transparent. But who will be the arbiters of transparency? Who will decide what these detailers can say or not say? Will these government “reps” have to play by the same rules as their pharmaceutical counterparts?

Most importantly, who will determine the difference between “communicating” these findings and “promoting” them? Alas, such finesse is unlikely under a regime of cost-think. As Orwell commented, Newspeak was constructed as to “give exact and often very subtle expression to every meaning that a Party member could properly wish to express, while excluding all other meanings and also the possibility or arriving at them by indirect methods.”

- US\$18 million to Ogilvy Public Relations Worldwide, Healthcare Division to create a publicity center and another contract for US\$8.6 million to create regional dissemination centers.

Importantly, what is the oversight mechanism? If academic detailers stray into off-label conversations, to whom does the FDA complain? Who does the Department of Justice investigate? Who pays the fine? *Quis custodiet ipsos custodes?* As currently designed, government detailing is a tool to increase government control over the practice of medicine and is a slippery slope toward the introduction of health care rationing and price controls. Congressional oversight must be required for the US\$42.3 million that AHRQ has already awarded for public and physician outreach.

To maintain an even (and accountable) playing field, perhaps the AHRQ should adopt what is already law in the State of Maine. In 2007, the Pine Tree State passed a law to “establish a prescription drug academic detailing program ... to enhance the health of residents of the State, to improve the quality of decisions regarding drug prescribing, to encourage better communication between the department and health care practitioners participating in publicly funded health programs and to reduce the health complications and unnecessary costs associated with inappropriate drug prescribing.”⁷ Unlike the

national program for government detailing, the Maine legislature included specific language regarding the oversight of educational materials:

Academic detailers shall observe standards of conduct in their educational materials and written and oral presentations as established by rules adopted by the department that are consistent with the following federal regulations regarding labeling and false and misleading advertising: the Food and Drug Administration labeling requirements of 21 Code of Federal Regulations, Part 201 (2007) and prescription drug advertising provisions of 21 Code of Federal Regulations, Part 202 (2007) and the Office of the Inspector General’s Compliance Program Guidance for Pharmaceutical Manufacturers issued in April 2003, as amended.⁷

As Rudyard Kipling said to the Royal College of Surgeons in London in 1923, “Words are, of course, the most powerful drug used by mankind. They enter into and colour the minutest cells of the brain.” We allow them to be usurped and corrupted at our own peril.

The Recovery Act of 2010 (aka “the stimulus package”) gave the Agency for Healthcare Research and Quality US\$1.1 billion to conduct (according to the HHS press release⁸) “comparative effectiveness research” into various “healthcare interventions.” However, that is not what Congress funded. Per the Recovery Act, that US\$1.1 billion was earmarked for *clinical* comparative effectiveness, not *comparative* effectiveness research. This is not splitting hairs. Enter cost-think. Those in favor of *comparative* effectiveness research favor large-scale trials to “compare” drugs and other health care “technologies, striving to show which medicines are most effective for any given disease state.” Is there a “more effective” statin? A “more effective” treatment for depression? However, how does one compare two molecules (or three or more) that have different mechanisms of action for patients that respond differently to different medicine based on their personal genetic makeup?

Comparative effectiveness relies heavily on findings from randomized clinical trials. While these trials are essential to demonstrating the safety and efficacy of new medical products, the results are based on large population averages that rarely, if ever, will tell us which treatments are “best” for any given patient. Two such studies, the Clinical Antipsychotic Trials in Intervention Effectiveness (CATIE) study and the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) study, were two such “practice-based” clinical trials, sponsored in part by the National Institutes of Health, to determine whether older (cheaper) medicines were as effective in achieving certain clinical outcomes as newer (more expensive) ones. The findings of both CATIE and ALLHAT were highly controversial, but one thing

is not: even well-funded comparative effectiveness trials are swiftly superseded by trial designs based on better mechanistic understanding of disease pathways and pharmacogenomics. Moreover, since most comparative effectiveness studies are underpowered, they don't capture the genetic variations that explain differences in response to medicines by different patients. Comparative effectiveness in its current form leads to a "one-size-fits-all" approach to health care, which means that it doesn't fit anyone particularly well.

Clinical effectiveness, on the other hand, measures outcomes on an individual patient level. Clinical effectiveness studies help us to understand how to design treatments based on patient variation rather than cost . . . the very definition of personalized medicine. As NIH Director Dr Francis Collins warned the board of the Patient Centered Outcomes Research Institute (PCORI), "Beware of the tension between CER and personalized medicine" (PCORI board of directors meeting, May 2011).

In sum, the differences between *comparative* and *clinical* effectiveness studies are profound, and by changing the actual legislative verbiage, the legislative intent is likewise altered. The implications for academic detailing and crucial, since these are the very studies that will be detailed.

The Devil Is in the Detailing

As Orwell wrote, no word in the Newspeak vocabulary was "ideologically neutral" and a great many were "euphemisms." Welcome to cost-think, where anything that has to do with health care reform cannot be spoken about in terms of cost but must be entirely based on the philosophy of reducing short-term costs. Nowhere is cost-speak more crucial than when it comes to *publicly bankrolled dissemination* of the findings of taxpayer-bank-funded and AHRQ-fielded comparative effectiveness research. An important and honest question to ask is whether or not these studies will be peer-reviewed before they are allowed to be released. (CATIE and ALLHAT were not.) Government-sponsored comparative effectiveness research, communicated through government detailing, is the first step toward allowing our government to push a restrictive formulary on more and more Americans. Unless we are aware and vigilant, such cost-think may very well lead to a single-payer system referred to in cost-think as "universal coverage." In reality, however, it will be nothing short of health care rationing. Government detailing is the razor-sharp tip of the spear.

Intent Dissent

What makes the FDA's Dr Bob Temple so endearing (and his opinions so enduring) is his blunt truth telling. At a recent conference hosted by the National Pharmaceutical Council and cosponsored by the National Health Council and WellPoint

("Asymmetry in the Ability to Communicate CER Findings: Ethics and Issues for Informed Decision Making"; February 9, 2012. Washington, DC), he stated his belief that regulations on product promotion should not impede companies from rebutting findings from comparative effectiveness research involving their products. This may not initially sound that important, but it's a clarion call for those who understand the imperative to systematically and scientifically counter the counter-detailing efforts coming thanks to the tens of millions of tax dollars earmarked for such efforts by the Patient Protection and Affordable Care Act (PPACA).

According to the *Pink Sheet*,⁹ "The subject of asymmetry in the reporting and commenting on CER findings has been a key point of discussion for [the National Pharmaceutical Council] as CER has taken on a more visible role within the health care debate. Some suggest manufacturers of products subject to CER might have difficulty discussing the findings of the research given FDA restraints on commercial speech." Perhaps not. Speaking at the February 9 conference, Dr Temple said there is "no FDA view . . . that drug companies are condemned to silence about their products outside of formal promotion or perhaps published articles. If there's something published that seems wrong, is based on poorly designed meta-analysis and so on, I don't see any impediment to answer that and companies do answer that all the time."

Indeed, Temple seemed surprised and displeased that industry has sat by while leading proponents of comparative effectiveness share their questionable conclusions. He commented as follows: "A recent example might be newspaper assertions that antidepressants have no long-term benefit and really don't work. This has been published repeatedly, and I'd like to see a rebuttal from the people who make antidepressants, because I think the published reports . . . are wrong. [FDA] may get around to rebutting, but somebody else might want to, and I don't think there is any impediment to doing that."

It should be noted that Temple qualified his remarks by saying (appropriately) that companies should be mindful of how FDA regulates speech when (and if) they decide to rebut wrong or misleading information from a comparative effectiveness research (whether or not it's government funded). "It is clear to me that a sponsor could correct or dispute a CER statement by a payer, or even the government, as long as the correction was not itself promotional." Which prompts the question, what precisely does "promotional" mean, and who is to judge? Temple gives a good example of how to avoid such a problem: "In recent months, we've seen companies disagree publically with meta-analyses, with epidemiologic conclusions they considered unsupported on methodologic grounds, and that's OK, although making their own [conclusions] probably would not be." In other words, it's not "promotional" to point out a comparative effectiveness study's design flaws and, therefore,

the errors of its conclusions. *If* such an approach is “compliant,” it opens up tremendous opportunity in countering so called “academic” detailing.

However, while Temple’s is a powerful voice inside the FDA, it is only one voice. If Secretary Sebelius’s interference in the agency’s Plan B decision is any indication—might not his view be similarly overturned by the mandarins in the Humphrey Building? After all, the comparative effectiveness studies under debate are funded by PPACA and fielded by AHRQ. Moreover, the current administration has not looked kindly on those who question either its philosophical motives or legislative methods. Industry is deemed guilty until proven guilty. The current *modus operandi* seems to follow Franz Kafka’s statement that “*My guiding principle is this: Guilt is never to be doubted.*”

Which brings us back to the question, *What does promotional mean?* A recent paper by Coleen Klasmeier, a former FDA attorney and currently the head of Sidley Austin’s FDA regulatory practice, addresses this issue head-on.¹⁰ She observed that “The FDA approach is one of *delicate balance*—of forbidding off-label promotion without undue incursion into the ability of physicians to obtain information about off-label uses from manufacturers.” This issue of “undue incursion” seems to dovetail nicely with Temple’s notion of focusing on design flaws and incorrect conclusions. But what of intent? Intent is in the eyes of the beholder. Where one person might see a robust discussion of study design, another might see promotional intent. The foundational problem, as Klasmeier eloquently pointed out, is the FDA’s reliance on “multifactorial tests rather than bright-line standards.”¹⁰

Plainly stated, regulators at the FDA (and particularly those who must address thorny First Amendment issues) embrace ambiguity over predictability. It gives them almost limitless power. Industry, on the other hand, wants and needs an evidence-based regulatory framework that provides predictable standards for their communications efforts. Bright lines. Predictability is power in pursuit of the public health. Minus such an effort, we get the troubling example of Par Pharmaceutical. In a pending First Amendment suit against the FDA,¹¹ Par contends the government is criminalizing its speech to health care professionals about the on-label use of its appetite suppressant Megace® ES (megestrol acetate) in settings where doctors prescribe the drug for both approved and unapproved uses. Par’s complaint, filed October 14 in the US District Court for the District of Columbia, seeks a preliminary injunction against government enforcement of FDA labeling regulations on the grounds they are harming Par’s First Amendment rights by chilling protected speech.

Par’s suit states that physicians more frequently prescribe the drug to treat wasting in non-AIDS geriatric and cancer patients and that the majority of prescriptions for the drug are

for off-label uses. Par also seeks a declaratory judgment that it may speak about the approved use to physicians who could prescribe it for that use, even if they are more likely to prescribe the drug for off-label uses. “Common sense dictates that the government cannot justify censoring a broad swath of truthful and valuable speech regarding lawful activity out of a desire to prevent other lawful activity,” a memorandum in support of the motion for preliminary injunction states. “And it is absurd to think that the government may imprison a person for engaging in truthful speech about a lawful activity that the government itself subsidizes.”

At issue in Par’s suit are provisions in the Food, Drug, and Cosmetic Act concerning “intended use” of a drug and misbranding. “If a manufacturer speaks about the on-label use of its drug in a setting where the manufacturer knows that physicians prescribe the drug off-label, the government interprets the FDA’s ‘intended use’ regulations to deem the manufacture to be expressing an ‘objective intent’ that physicians prescribe the drug off-label,” Par’s memorandum states. In a press release announcing the suit,¹² Par said it hoped to “elicit tailored and constitutionally permissible regulatory guidance to ensure that physicians may be kept abreast of valuable, on-label information about prescription drugs to aid in their provision of quality and informed patient care.”

If a company can be challenged when it discusses strictly on-label uses of a product, how much more convoluted, challenging, and intimidating will it be to challenge a government-funded and government-detailed comparative effectiveness study? Disputing comparative effectiveness studies, or any research, need not fall into the chasm of promotion (off-label or otherwise). To lump scientific discourse into this slippery silo is to court both agency action and political attention. As Klasmeier¹⁰ noted, “The off-label problem reflects the accretion of administrative interpretations over the years . . . the *commercialization* of an investigational new drug is not to be construed to interfere with a manufacturer’s entitlement to engage in *scientific exchange*.”

Is it not the case that debating the flaws of a research study scientific exchange, even if (and especially when) such exchanges raise questions about conclusions that are contrary to any given company’s marketing and sales objectives? How does the issue of intent play into compliance when legitimate scientific exchanges also impact promotional considerations? On which side should regulators err? The answer is as easy as it is difficult—regulators should err on the side of the public health. Perhaps the best precedent is FDAMA Section 401, which expressly permits companies to provide reprints of peer-reviewed medical journal articles on off-label studies (as long as they have a pending supplemental application with the agency).

Let us remember the astute observation of William Blake that, “A truth that’s told with bad intent, beats all the lies you can invent.” To paraphrase Douglas MacArthur, “The patient, and the patient, and the patient.”

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