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1 The objection to government involvement

"The US is unique because it alone is the source of half of world-wide profits that provide the payoff for the complex, lengthy, and expensive process of developing new treatments. When other nations construct their health-care systems, they ignore the impact of their pricing policies on R&D incentives. As the dominant R&D funding wellhead, we do not have that option.

Competitive markets have generated the prices and the profits necessary to induce a steady flow of medical innovation in this country. A public plan option would tend to dismantle that system. The people in charge will not know how to set reimbursement levels to motivate reasonable R&D efforts, and there is no reason to expect them to try. In public plans, the tried-andtrue method is to push the prices of suppliers down until something gives ... and then to ease up. That is a destructive approach to medical technology R&D." (Calfee, 2009)

2 The facts of government involvement

"The US government currently accounts for almost half of all spending on health care in this nation. The regulatory role of the government is pervasive." (Gruber, 2008, p. 572)

"unlike other businesses, drug companies are dependent on the public for a host of special favors — including the rights to NIH-funded research, long periods of market monopoly, and multiple tax breaks that almost gurantee a profit." (Angell, 2004)

3 What do drug companies research?

"In the past, large pharmaceutical companies were the primary sources of antibiotic research. But many of these companies have abandoned the field.

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'Eli Lilly and Company developed the first cephalosporins,' Moellering told me, referring to familiar drugs like Keflex. 'They developed a huge number of important anti-microbial agents. They had incredible chemistry and incredible research facilities, and, unfortunately, they have completely pulled out of it now. After Squibb merged with Bristol-Myers, they closed their antibacterial program,' he said, as did Abbott, which developed key agents in the past treatment of gram-negative bacteria. A recent assessment of progress in the field, from U.C.L.A., concluded, 'FDA approval of new antibacterial agents decreased by 56 per cent over the past 20 years (1998-2002 vs. 1983-1987),' noting that, in the researchers' projection of future development only six of the five hundred and six drugs currently being developed were new antibacterial agents. Drug companies are looking for blockbuster therapies that must be taken daily for decades, drugs like Lipitor, for high cholesterol, or Zyprexa, for psychiatric disorders, used by millions of people and generating many billions of dollars each year. Antibiotics are used to treat infections, and are therefore prescribed only for days or weeks. (The exception is the use of antibiotics in livestock, which is both a profit-driver and a potential cause of antibiotic resistance.)" (Groopman, 2008)

4 Market incentives and research

"A few decades ago, medical schools did not have extensive financial dealings with industry, and faculty investigators who carried out industry-sponsored research generally did not have other ties to their sponsors. But schools now have their own manifold deals with industry and are hardly in a moral position to object to their faculty behaving in the same way. A recent survey found that about two thirds of academic medical centers hold equity interest in companies that sponsor research within the same institution. A study of medical school department chairs found that two thirds received departmental income from drug companies and three fifths received personal income. In the 1980s medical schools began to issue guidelines governing faculty conflicts of interest but they are highly variable, generally quite permissive, and loosely enforced.

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Because drug companies insist as a condition of providing funding that they be intimately involved in all aspects of the research they sponsor, they can easily introduce bias in order to make their drugs look better and safer than they are. Before the 1980s, they generally gave faculty investigators total responsibility for the conduct of the work, but now company employees or their agents often design the studies, perform the analysis, write the papers, and decide whether and in what form to publish the results. Sometimes the medical faculty who serve as investigators are little more than hired hands, supplying patients and collecting data according to instructions from the company.

In view of this control and the conflicts of interest that permeate the enterprise, it is not surprising that industry-sponsored trials published in medical journals consistently favor sponsors' drugs—largely because negative results are not published, positive results are repeatedly published in slightly different forms, and a positive spin is put on even negative results. A review of seventy-four clinical trials of antidepressants, for example, found that thirtyseven of thirty-eight positive studies were published. But of the thirty-six negative studies, thirty-three were either not published or published in a form that conveyed a positive outcome. It is not unusual for a published paper to shift the focus from the drug's intended effect to a secondary effect that seems more favorable. ...

It is simply no longer possible to believe much of the clinical research that is published, or to rely on the judgment of trusted physicians or authoritative medical guidelines. I take no pleasure in this conclusion, which I reached slowly and reluctantly over my two decades as an editor of *The New England Journal of Medicine*." (Angell, 2009)

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