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1980s deregulation led to modern corruption

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The abrupt resignation of Dr. Jose Baselga in September 2018 laid bare the corrupt influence wielded by drug and medical device-makers over medical research and the unintended consequences of deregulation. Baselga, the now-former chief scientific officer of Memorial Sloan Kettering Cancer Center, resigned after reporting by ProPublica and *The New York Times* revealed that he repeatedly failed to properly report millions of dollars in industry payments from companies whose profits he directly influenced.

According to the reporting, Baselga's deception was just one example of a rampant problem in academic medicine. Drug and medical device makers seek to influence physicians and health-care institutions in myriad ways, including board memberships, gifts, honoraria and direct payments. Extensive research and practical experience have illustrated how these relationships create conflicts of interest and "distort" the practice of medicine. Research has shown that even small gifts influence physicians' prescribing habits and larger payments can effect not only the design of clinical trials but also the actual reported results.

One recent example cited by the *Times*/ProPublica is the opioid epidemic. Drugmakers in search of increased sales inundated physicians with gifts and consulting fees and convinced them to ignore the risks to patients and to "liberally" prescribe highly addictive painkillers.

Baselga was a superstar in cancer research and his work led to the discovery, patenting and FDA approval of numerous cancer treatments, including the blockbuster drug Herceptin, a treatment for breast cancer. But he stood to personally gain from the approval of the drugs he studied.

For example, in statements to industry analysts and the American Association of Cancer Research, Baselga lauded two drug trials that were widely considered failures while accepting millions of dollars in payments from Roche, the sponsors of those studies. He also apparently failed to disclose his financial conflicts to dozens of journals, including at least one he edited. He also served on the boards, with hundreds of thousands of dollars in compensation, of companies that did business with Sloan Kettering or whose products he was supposed to evaluate objectively.

According to Dr. Marcia Angell, the first woman to serve as the editor-in-chief of the *New England Journal of Medicine*, and currently at Harvard Medical School, the seeds for this mess were sown via deregulation. Before the 1980s, drug manufacturers had little access to researchers and clinical subjects. They handed out grants to institutions and physicians to study their drugs and waited for the results. They did not design the trials, analyze the data before publication and they did not write the articles or control publication.

In the 1980s, Angell notes, that all began to change, in part because of a federal statute that allowed researchers and their affiliated institutions, including the National Institutes of Health, to patent their discoveries and license them to drug companies. That change essentially made clinical researchers business partners with the drug companies. Worse, writes Angell, it gave companies direct access to "key opinion leaders" in the parlance of the industry, the people who write textbooks; write, review and edit medical journal articles; and speak at conferences.

As Angell notes, it is human nature to feel kindly toward colleagues and those with whom we collaborate. It is also difficult to ignore the potential for personal gain. These biases can be introduced into research in a number of ways, including the suppression of negative results. Angell cites a review of 74 clinical trials of antidepressants which found that 37 of 38 studies that reflected favorably on the drug studied were published while 33 of 36 negative studies were either never published or were published in ways that conveyed positive results.

In response, many commentators have called for more transparency and more stringent requirements for disclosure but this misses the point. Disclosing conflicts does not obviate their effects. As Angell puts it, disclosure is merely a way of saying caveat emptor when the whole point of objective medical research is that the buyer should not have to "beware."

The only solution is to remove the influence of money and the conflicts it creates. As Angell proposes, researchers should not be offered or accept any payments from persons or entities with an interest in the drugs being studied. Further, physicians should not be offered or accept any gifts from drug companies. This is not as radical as it seems. Indeed, since the early 1990s, the federal government has prohibited its employees from accepting any gift worth more than $20 from a regulated industry or given because of the employee's official position. If a private who works at an Army medical center cannot accept a meal at Chili's from a drug company representative, why on earth do we allow physicians who are supposed to protect our safety from taking much more? CL

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