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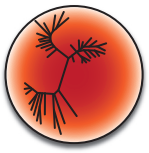

Science and Money: Problems and Solutions

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Scientific research, like carpentry, farming, manufacturing, or banking, is a form of business. The business of science is to produce new discoveries and innovations that advance human knowledge and society. Science, like any other business, involves investments of money, property, human resources, facilities, and capital. The global spending on research and development (R & D) is $1.6 trillion annually, or 1.8% of the world's gross domestic product (1). R & D plays a major role in economic development by producing new knowledge and technologies and providing individuals with high-paying jobs that support many other jobs (9). Private industry funds the majority of R & D conducted around the world. In the US, 71% of R & D funding comes from industry, followed by government (21%) and private foundations (4%) (1).

Scientists, sponsors, and institutions usually have financial interests related to the outcome of research. Scientists receive salary support for their work and may have intellectual property rights, such as patents, related to their research. They may also own stock in companies that fund their research or have relationships, such as consulting agreements, with those companies (9). Companies that sponsor research have an interest in producing research results that can support the development and marketing of their products or services. Companies may also own intellectual property related to their research. Institutions receive funding through contracts or grants with research sponsors and may also own stock in companies that fund research. Institutions often have collaboration agreements with companies and receive gifts from companies. Institutions may also own intellectual property related to research.

Although most of the debate about financial interests in research has focused on ownership of stock or intellectual property or relationships with private research sponsors, it is important to realize that salary support can also have a significant impact on scientific behavior. Decisions concerning hiring, tenure, and promotion made by academic institutions are usually based on a scientist's ability to publish, develop intellectual property, and obtain grants or research contracts (9). Many institutions require investigators to support their salaries by obtaining contracts or grants and have come to depend on the indirect income provided by grants or contracts to cover operating expenses. Some scientists, such as post-doctoral fellows, are supported by "soft money," which means that their salaries are supported entirely by grants or contracts obtained by investigators. If these contracts or grants are not renewed, these researchers may lose their jobs. Some institutions provide researchers with stipends or salary increases for publishing papers in top-tier journals (9).

Many scientists and scholars are concerned that financial interests can threaten the scientific community's adherence to methodological and ethical norms, such as honesty, objectivity, openness, social responsibility, and protection of research subjects (5, 9, 8, 3, 7). Scientists who have financial interests related to their work may distort their research to produce desired results, fail to publish or share data or methods appropriately, or violate ethical or legal rules. Research sponsors may manipulate study designs or data analysis and interpretation to produce outcomes that favor their interests, or suppress unfavorable data and results. Institutions may sign contracts that allow private companies to prevent academic scientists from publishing data or results or they may accept gifts that give industry donors some control over research or the curriculum. Institutional officials may look the other way when well-funded investigators are accused of misconduct, or they may place pressure on oversight committees to approve lucrative studies (9).

There are many well-known cases in which financial interests have adversely impacted scientific integrity. For example, in the early 2000s, scientists funded by the pharmaceutical company Merck did not publish data showing that its drug Vioxx increased the risk of heart attacks and strokes, and several pharmaceutical companies failed to publish data showing that their anti-depressant drugs increase the risk of suicide in adolescents (9). In the 1990s, tobacco companies conducted secret research on the addictive properties of nicotine while claiming that cigarettes are not addictive (8). In 1995, the pharmaceutical company Boots forced University of California pharmacologist Betty

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Dong to withdraw a paper accepted by the *New England Journal of Medicine* showing that its thyroid medication is not superior to several generic medications (9). In 1999, Jesse Gelsinger died from a severe immune reaction to an adenovirus vector he received in a Phase I gene therapy trial in which the investigator and the institution had significant financial interests (stock and patents) that were not properly disclosed during the consent process. Gelsinger also was not properly informed about the risks of the treatment identified by previous animal studies (9). In 2005, University of Vermont researcher Eric Poehlman admitted to fabricating and falsifying data over a ten-year period on 15 federal grants worth $2.9 million. Poehlman, who served a year and a day in federal prison and was fined $196,000, claimed that he manipulated data because he felt pressure to maintain grant funding to support himself and his research staff (12).

Numerous empirical studies have highlighted potential funding biases by demonstrating statistically significant associations between private sponsorship and research outcomes (10). For example, a study of research on calcium channel blocking drugs found that 96% of authors who published studies reporting outcomes favorable to the use of calcium channel blockers had financial relationships with corporate sponsors, while only 37% of the authors who published studies that did not favor the use of calcium channel blockers had such relationships (14). A study of publications evaluating the economics of cancer treatments found that 38% of studies without industry funding reported negative results, while only 5% of articles with industry funding reported negative results (4). Another study of cardiovascular clinical trials found that publications that disclosed industry funding were more likely to report positive findings than those not funded by industry (11). Three systematic reviews of over 40 publications examining the relationship between sources of funding and research outcomes found that studies with industry funding were more likely to report results that favored the company's products than studies with independent sources of funding (6, 2, 13).

Although it is widely acknowledged that financial interests can threaten the integrity of science, it is important to realize that having an economic stake in the outcome of a study does not automatically invalidate or taint one's research. Most researchers with financial interests related to their work conduct good research, and most sponsors and institutions do not manipulate study design, execution, management, or oversight to promote their financial interests. Fortunately, the egregious examples mentioned above are the exception rather than the rule (12). Furthermore, many of the biases related to funding may not result from deliberate attempts to manipulate research outcomes but from subconscious influences on cognition and behavior. Researchers may not even be aware of how financial interests impact their judgment and decision making. Biases related to the publication of positive findings may result from editorial decisions to not publish studies with negative results, rather than deliberate attempts to suppress these results. The funding decisions made by companies may skew the research record because they may decide to only fund studies that are likely to promote their interests, not because they manipulate the process of research (10).

Because science is a business replete with many different types of financial interests, eliminating or drastically reducing them is not a realistic option. The best approach to dealing with financial interests in research is to implement policies designed to minimize or mitigate their impact on scientific integrity (9). Some of these include:

- Disclosing financial interests to institutions, government agencies, journals, human research subjects, and other parties who need to know about them;
- Managing individual and institutional financial interests related to research (management may include the use of special committees to review and oversee projects involving financial interests likely to impact research integrity);
- Prohibiting financial interests which are difficult to manage;
- Penalizing researchers who violate disclosure policies;
- Educating scientists, students, and staff about issues and policies related to financial interests in research, including not only private funding but also intellectual property, grant funding, and salary support;
- Scrutinizing contracts with private companies to ensure that they do not include provisions that allow companies to prevent the publication of academic research;
- Requiring registration of clinical trials in a public database so that researchers may learn about studies that are being conducted;
- Sequestering research oversight at academic institutions from contract and grant management, technology transfer, and fundraising;
- Providing government funding for comparative effectiveness research in clinical medicine to counteract biases resulting from industry funding;
- Requiring researchers to make supporting data and methods available as a condition of publication.

Institutions, journals, and government agencies have already begun implementing most of these policies. Further policy development may be needed to protect the integrity of scientific research. However, policies alone will not protect science from the adverse impacts of financial interests. The responsibility for safeguarding the integrity of research ultimately rests with scientists, who must uphold the ethical and methodological standards that apply to their work.

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