Pharmaceutical companies liable for fraudulent research by subcontractors

'The 1990s saw the uncovering of widespread fraudulent data on applications for the approval of generic drugs …'

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In the near future pharmaceutical companies that rely upon subcontractors to carry out their research and testing of products might find themselves being sued under the Federal False Claims Act because of errors, omissions and misrepresentations to the FDA in the new drug application (NDA) process – even if they had no knowledge of their subcontractors' falsifications. Outsourcing makes financial sense to pharmaceutical companies and has even protected parent companies from liability, but it is just a matter of time before major litigation exposes a weak link in the way drugs are brought to market. Up to now, federal prosecutions have largely been brought against individuals who falsified research data, not corporations. For example, a prominent doctor was convicted of research fraud in clinical studies of the psychiatric drug Anafranil® (Novartis; http://www.novartis.com) [1]. Another doctor pleaded guilty to conspiring to falsify drug test data and making false statements to the FDA in clinical studies for anti-inflammatory arthritis drugs [2]. The doctor had submitted thousands of falsified reports in at least 18 experimental drug studies for nine different drug manufacturers. In these and other reported cases, corporations fortuitously escaped prosecution under the Federal False Claims Act because, typically, the duplicity of their physician and/or subcontractor was either discovered before the FDA approved their drugs, or was not a determining factor in the approval of the drugs. However, if the falsified research is discovered after FDA approval of the drug, and the falsified research influenced the decision of the FDA, then pharmaceutical companies could be held liable. Lawsuits involving the recovery of (what are likely to be) millions of dollars from pharmaceutical companies, as well as incalculable amounts of bad press, will amount to major trouble for the industry as a whole.

Catastrophic risk

The language of the FDA guidelines for 'good clinical practice' makes it clear that pharmaceutical companies are responsible for the actions of their subcontractors: 'A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO (contract resource organization), but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor.' Lawyers who file suit under the *qui tam* provisions of the Federal False Claims Act are sure to argue that if the FDA were to approve a product based upon false research data, it might not be safe or effective. Consequently, such a drug would not be eligible for reimbursement under federal healthcare programs, and any claims submitted for payment would be fraudulent and the company could be held liable. Under the powerful measures of the Act, the financial penalty to a pharmaceutical company could be catastrophic – such a penalty is calculated at three-times the gross sale of the drug, payable to the United States, with a hefty percentage going to whoever exposed the fraud.

Of course, falsifying pharmaceutical research data is nothing new. The 1990s saw the uncovering of widespread fraudulent data on applications for the approval of generic drugs that pharmaceutical companies submitted to the FDA. The difference is that, after disclosures of criminal behavior by major corporations such as WorldCom and Enron, the public has zero tolerance for corporate wrongdoing. As a result, it is no longer realistic for corporations (particularly pharmaceutical companies) to assume that they can get away with anything, even if they did not mean to.

Even ethical manufacturers are at risk

The Internet has made the exchange of vast amounts of information commonplace. Nobody can protect a secret misdeed, particularly a potentially culpable corporation. Research fraud will no longer go undetected for long. As more and more high-profile whistleblower and False Claims Act cases are making headlines, average men and women sharing the public's outrage against unscrupulous corporations are becoming increasingly emboldened to

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expose their employer's fraud. In addition, reeling from business scandals and excesses, Congress and the general public are looking for prime targets at a time when federal monies are scarce or non-existent because of our international commitments, sagging economy and small-government policies. In short, the external environment could not be worse for an ethical pharmaceutical company that has placed its trust in, what might turn out to be, an unscrupulous subcontractor, let alone a company that set out to defraud the government and American consumers.

Because no cases for fraudulent research have as yet been adjudicated under the Federal False Claims Act, pharmaceutical companies should use the breathing-space they have until the first corporation falls to their collective advantage. Ethical corporate leaders need to take steps to be certain that they have policies and procedures in place that protect their company from unscrupulous research subcontractors, and should also move quickly to establish industry-wide standards.

Inclusion of subcontractors in compliance effort

Initially, any pharmaceutical company that enters into a relationship with a CRO should do so only after fully vetting the company in as objective a way as possible, including unannounced on-site inspections of CRO facilities, private off-site interviews with researchers and an in-depth review of the history of the organization providing responsible research. In addition, there should be a firewall between a sponsoring pharmaceutical company and its CRO, so that marketing, production and other pressures the pharmaceutical company might bring to bear, which could potentially compromise a responsible research process, will not be placed upon the CRO. Finally, the compliance program of the pharmaceutical company should incorporate the activities of the CRO, from access to the compliance hotline to internal investigations. The upfront cost of what might at first appear to be an unaffordable, even unnecessary, process might prove less expensive than a draining (even destructive) litigation should a research process be compromised.

Whatever strategies the pharmaceutical industry might adopt, executives must be committed to constant vigilance and reassessment of their policies and procedures. There is no quick or one-time fix. Companies must continuously retrain their employees in ethical behaviors and insist that their research subcontractors do the same. Such compliance programs are, in fact, their best defense against prosecution under the Federal False Claims Act, should a complaint be made against them. Companies that can show they have done everything possible to avoid fraud are not likely to be charged or convicted of it.

There really is no alternative, even though some companies might delude themselves into thinking that this is not an important issue. Unless pharmaceutical executives take the initiative to ensure impeccability in their research data, the government will eventually do it for them, particularly after one major case breaks that highlights the incidence of a patient being harmed. The law of averages will meet the present business climate, to the distinct disadvantage of an industry that could and should have known better. Anyone who suggests that the upfront costs of vigilance would break the corporate bank should consider the long-term effect of losing major revenue if the FDA reacts with more stringent guidelines for research protocols and slows its approval process to allow for greater oversight and review of research. Self-policing is always preferable to government intervention. The choice is up to the industry, but it is running out of time.

References

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