Case Study:- pharmaceutical company

Case Study: As the head of corporate audit for a major pharmaceutical company, I was involved in the lengthy approval process that the Food and Drug Administration requires before a new drug can be brought to market. The reviewer for the FDA was asking some tough questions about the data supporting our application to market a new drug. Although I managed to answer the reviewer's questions to his apparent satisfaction, doubts were beginning to form in my own mind about the reliability of the data I was defending, so I instructed my staff to get photocopies of the original research reports for me as soon as possible. The photocopies provided evidence of 'double books'. The raw data in the original reports were entirely different from the data in our FDA application and showed the new drug failing every required test. I had heard rumors of other questionable conduct by the project director, and I suspected that he was implicated in the falsification of the data, although I had no proof for any accusations. I rejected the idea of blowing the whistle on the company by telling everything to the FDA and decided instead to follow the procedure outlined in the company's own whistle-blowing policy. Accordingly, I prepared a report stating only the facts that I could document, and I sent it to the next highest level above the person involved, which in this situation was the legal department of the corporation. My internal whistle-blowing prompted a quick response. I was summoned to meet with the board of directors which had a team of lawyers from an outside firm present. The original research reports had apparently been destroyed, but there was no question about the authenticity of the photocopies that I still retained because the raw data were accompanied by the researcher's signatures and the dates of entry. After friendly but close questioning, the board of directors offered me a 'deal'. They would give me all of the resources that I needed to get the drug approved by the FDA, but they promised that the drug would never be marketed. The board intended to correct the problems within the company (and the project director soon resigned), but it wanted to avoid the embarrassment of public exposure. The board's plan was to request that approval of the drug be withdrawn afterward by telling the FDA that mistakes had been made in the marketing projections. I accepted the deal and succeeded in getting the drug approved. The board kept its word, and 10 years later the drug is still not on the market. After my 'deal' with the board, other changes were made. Corporate policy was revised so that I no longer had ready access to company records. The FDA has the authority to conduct surprise audits at any time, and the policy had been (in the past) to allow my office to mimic FDA audits, so that the company would always be 'FDA-ready'. Under the new policy, audits must be prearranged with the department involved, and the department can stop an audit and reschedule it at any point. Finally, the department is allowed to review the audit report before it is submitted. To my knowledge, there has been no repetition of the events of 10 years ago, but my ability to uncover such misconduct has been severely limited. Oftentimes I wonder whether I should have accepted that 'deal'.