Tendexta: Charting the Way Forward Responsibly

Tendexta is a large pharmaceutical company, widely regarded as “one of the good guys” in an industry that, for a variety of reasons, has something of an image problem. Tendexta has developed drugs for the treatment of depression and rheumatoid arthritis, as well as drugs for the treatment of ulcers and heartburn. These drugs have earned the company billions of dollars and patents more or less guarantee a similar return for the remainder of the patent-protection period. (The newest of these drugs has 8 more years of patent protection; the oldest has three more years of patent protection.) Tendexta has an analgesic in development that holds great promise; phase 3 clinical trials are underway and everyone on the development team is sanguine about FDA approval. (Phase 3 clinical trials, which follow successful phase 2 trials that establish the drug’s efficacy, gather additional information about safety and effectiveness, study different populations and different dosages, and use the drug in combination with other drugs.) Because the drug, Profexadil, is expected to revolutionize pain management and palliative care, it will receive priority review by the FDA. “The goal for completing a Priority Review is six months.” (http://www.fda.gov/Drugs/ResourcesForYou/SpecialFeatures/ucm279676.htm)

Working to keep up with the increasingly rapid pace of advancement in science and medicine and looking to better position itself in an industry profoundly impacted by “the genetic turn,” Tendexta acquired Johnson-Bellwood Research Group (JBRG), a biotechnology firm doing cutting edge research utilizing DNA. According to press reports, JBRG’s research is “incredibly innovative”; “it is moving the boundaries of medical science.”

JBRG’s clients have included universities, university medical centers (public and private), hospitals, and the research arms of various companies in the healthcare industry. Knowing that their cutting edge technology is powerful and subject to only minimal regulation, the leadership of JBRG, mostly scientists and bioengineers, carefully monitored licensing and sales of its technology: JBRG investigated potential clients and made its technology available only to those whose proposed applications of the technology would constitute what they called “bona fide use” (i.e., “a legitimate use carried out in good faith”). To be sure, determining what was and was not bona fide use presented some challenges. For example, some potential clients planned to use the technology in researching the gene tic basis of diseases commonly found in specific ethnic groups. The potential benefits of such research were clear, but JBRG was concerned about the ways in which that information might be used in the future, how the data would be stored and managed, and whether or to what extent the privacy of those whose genes were the subject of research would be protected. This last was of special concern with private researchers who, unlike researchers at universities receiving federal grant support, for example, would not be subject to oversight by an Institutional Review Board or the ethical constraints that fall under the rubric of the responsible conduct of research (RCR) embraced by the National Institutes of Health (NIH) and the National Science Foundation (NSF). These concerns are, of course, ethical concerns. But there were legal concerns as well, for example, potential liability for wrongful use of JBRG’s technology. After all, novel (some would say crazy) legal theories have been known to carry the day at great cost to businesses that scarcely could have foreseen harm that later becomes the basis of liability in a court of law.

Tendexta has a large stable of lawyers to handle legal questions.

Tendexta’s Board of Directors has hired your team to help them deal with the ethical concerns
associated with the acquisition of JBRG. Put another way, the Tendexta Board is looking to you to help them chart the way forward responsibly.

One key question is whether JBRG’s leadership was right in thinking that they had an ethical obligation to vet potential clients using a criterion of bona fide use. There are questions about the criterion of bona fide use as well, of course, though they would be moot if there is no obligation to vet potential clients. While concerns that insurance companies might discriminate against people with certain genetic markers have subsided with implementation of the Affordable Care Act, questions about privacy still loom large (primarily in the form of challenges regarding data storage/security and management).

The Board is keenly interested in consumer applications of the technology (entry into the “personalized healthcare market”). However, recent developments have given them pause, in particular, the recent letter from the Food and Drug Administration (FDA) to 23andMe (https://www.23andme.com) directing it to stop marketing its personal genetic testing kits “until such time as it receives FDA marketing authorization for the device.” (http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm376296.htm) Consequently, the Board has indicated that in addition to matters such as those discussed briefly above, in helping Tendexta map the way forward your team should address two questions in particular:

1. What are the ethical concerns associated with entry into the personalized healthcare market?
2. (a) What would Tendexta’s ethical responsibilities be if it were to move into this market? (b) What would Tendexta need to do to fulfill them?