

Creating benchmarks for ethical pharma, interview with Bioethics International's Jennifer Miller

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Jennifer Miller is the founding president of Bioethics International (BEI), a US-based non-profit organization which aims to improve the ethics and transparency of health care innovation and delivery.

A major focus for BEI is around access to medicines, and as part of this Dr Miller has launched the Good Pharma Scorecard (GPS), an annual ranking of pharmaceutical companies and new drugs on specific ethics and population health performance indicators.

The aim of this index is not so much to highlight wrongdoing, but to recognize good practices in companies, improve trustworthiness and incentivize reform.

Dr Miller explains why this focus on pharma is so necessary to ensure better public health outcomes, and why addressing industry issues is so critical.

“The pharma sector is one of the major determinants of access to medicines and the pharma industry sponsors 70% of the clinical trials that lead to approved products, so they're really a driver of innovation and in people getting the cures that they need,” she says.

“When you think about the pharma industry, you notice their noble statement, to advance therapies that alleviate suffering and help people lead better lives, but besides that and some of the great products that they have created, you also notice that they really struggle with their public perception.

“They have a huge amount of mistrust in the USA and increasingly elsewhere. Polls show that in the USA, only 12% of the population trust pharma companies to be honest and ethical, and 70% think they put profits before people. A mere 17 years ago you could find the pharmaceutical industry ranking among the most trusted and valued industries in the world.”

Huge variance in transparency

The idea behind the GPS is to find out the areas around which stakeholders have concerns with across different companies, use these to develop standards for the industry and judge how firms are performing against these benchmarks, before using the findings to develop reform strategies.

“We decided to create a ranking that is created every year, so every time a set of drugs is approved, we will score every drug for its trial transparency, and then we will rank all of the drugs along with their sponsors, so every new drug and every sponsor will be ranked and here we will signal where there are best practices and then help the other areas that aren’t scoring so well.

“You can see over time if they’re improving their processes if they score better every year. It will create a pathway for reform, thereby creating a trustworthy health care innovation sector,”

BEI identified the main areas of concern as it studied a series of drugs which were approved by the US Food and Drug Administration in 2012 that were manufactured by the 20 largest pharma companies.

These were around clinical trial design and concept, transparency of the studies, marketing of drugs and access to them for patients.

Findings of how companies were performing against the benchmarks drawn up in the pilot index, published in 2015, show a huge variety and underline the need for an initiative like the GPS, Dr Miller says.

So while UK pharma major GlaxoSmithKline (LSE: GSK) and US health care giant Johnson & Johnson (NYSE: JNJ) achieved 100% transparency scores, for example, in other instances companies’ compliance with transparency laws was found to be 0% in relation to a handful of drugs.

“The industry will slowly improve its practices over time as it learns that there are ways to act and that people care and want to see those better ways,” Dr Miller says.

A tool for regulators

Laws and the penalties they carry should not be the only means of encouraging change, Dr Miller adds.

“The other and better way is to create a knowledge exchange platform so they can learn and be inspired that there is a better way, that there are best practices, and what I have

found with the GPS was that a lot of companies didn't realise that their peers were doing things differently."

For this reason BEI tries to bring companies together once or twice a year to give them a knowledge exchange opportunity and the chance to learn from those developing drugs in the most transparent, ethical ways.

The GPS can also be a useful tool for regulators, Dr Miller says.

She explains: "The FDA has the ability to impose a \$10,000 a-day penalty for failing to disclose clinical trials that are legally required to be disclosed, and it has never once imposed that fine over the last nine years.

"So passing laws is one thing but you also need to monitor and enforce them, and that takes a lot of resources so the GPS, because it's benchmarking compliance with the law, also helps support regulatory bodies. It helps to show the FDA that if it wanted to do some targeted enforcement or monitoring, it might have an idea where to focus."

The benchmarks used in the GPS are also now being adopted by trade associations as they try to improve standards among their members, and showcase the companies doing the best against these measures. BEI also plans to introduce an annual award to the top scorers.

Even with the promise of improved practices and potential reform, does Dr Miller believe that the needs of pharma companies to make money, and those of payers and patients to have access to affordable drugs, are compatible?

"I think when large amount of money are on the table there are always temptations to take shortcuts to reach the money," she says. "Money is always an influencer, but at the same time money can also contribute to professionalization, and professionalization has the potential to create a set of standards and best practices that are accepted by the profession.

"So in that sense you want to stack the incentives for as much good as you can. That's what I hope the GPS does, it adds one more incentive to be good and to be recognized, to be awarded for being that champion and that leader in ethics."