

A Code of **ETHICS**

► *Mike Rea, CEO of IDEA Pharma, talks about the need for a unifying code of ethics for the pharmaceutical industry.*

PV: Why do you believe a “Code of Ethics” is necessary for the pharmaceutical industry?

REA: I think the first reason is that there isn't one. That, for me, creates a fundamental dissonance between the people I see every day, who want to behave ethically, and want to be seen doing so, and the reactive messaging we see so much on issues such as pricing. We're all very aware that dinner parties are not the place to air our occupation, even if what we do every single day is about the greatest thing anyone in any industry does. If we are to get ahead of our own reputation, it isn't enough to create issue-by-issue arguments. We need to, transparently, agree what we believe is the right thing for our industry, and then use that to frame our arguments. If you tried to derive our ethical view from the industry's current messaging, it is either 'no issue here, look at those other guys...' or 'do you want new medicines, or not...?'

PV: Were you surprised that no such guidance document already existed?

REA: Yes. My starting question was 'where is it?' Clearly, we are surrounded by all kinds of codes: medical ethics, promotional codes, ethics committees. But when it comes to finding comfort that our ecosystem is sustainable, that it is okay for us to make a certain profit — and that the world doesn't mind — the code is nowhere to be found. There are great initiatives like the ethics scorecard by Dr. Jennifer Miller at NYU, but no widely adhered to document. That was my first pursuit — to find the document. And I found none.

PV: Why aren't the PhRMA code and other such guidelines sufficient?

REA: I'm mindful that there are many groups that have the interests of the industry at heart, and where they can they try to self-police — in preference to being policed from outside. But the lobbying that tries to conserve the way things are, I feel, is also responsible for the reputation challenges the industry has. For such a wonderful industry to have such a dreadful reputation may not be everyone else's fault. What I have found have been a lot of 'codes of conduct,' which are often not driven by

values, but by legal frameworks — what is allowable, or even, what can we get away with without attracting too much attention? That is one reason that we may not call this a code; that suggests policing, and that absolutely is not the intent. I'm also keen, where possible, to invite groups such as BIO, EFPIA, and PhRMA to participate, but not to drive.

PV: What do you envision the “code” would cover and or entail?

REA: That is one of the first questions. Currently, I am looking at two outputs: a simple document, issued annually, and a research program. The expectation is that it is transparent, including voices such as payers, patients, and physicians in the discussion. So much of 'ethics' is about airing the questions, and the logic of debate. I don't want this to get into the weeds on pricing, for example, as there is no 'right' answer to an issue like annual price rises expressed in percentages. But there is a 'right' answer with respect to the sustainability of the innovation model and our ecosystem; these are the kinds of questions I am keen to drive toward conclusion soon.

PV: What do you anticipate will be the biggest obstacles in creating such a doctrine?

REA: The first expectation was that there may be obvious questions. Why am I doing it, for example, is the first one. My answer is 'why not?' I am not an ethicist, so I am not starting with an assumption that I know what good looks like. I am hoping that my PharmaVOICE Red Jacket gives me enough of a platform to be heard, but I'm nowhere near the status that would mean this will be greeted with skepticism. But I am very certain that if we do the right things, reputation will follow. I don't expect all parts of our industry to align behind it, so to start the focus will be on the 'ethical' pharma industry: science and R&D-led organizations in pharma and biotech. There's no point trying to solve for the practices of the generics companies from the start.

The good news is that so many of the heads of R&D of major pharma have immediately grasped the opportunity to be involved, and it has generated a lot of enthusiasm from all sides, so my feared obstacles may well not be whether it is needed, but down the line, as we get into detail.

PV: How would the code be structured?

REA: My current expectation is that we will have

The Good Pharma Scorecard

Jennifer Miller, Ph.D., is the founding president of the nonprofit, Bioethics International.

Dr. Miller's current work addresses the ethics and governance of healthcare innovation, focusing on how clinical trials are designed and conducted, data-sharing, drug marketing, and the accessibility of medicines. Dr. Miller created an index — The Good Pharma Scorecard — that ranks pharmaceutical companies and new drugs on their ethics and public health performance to help recognize best practices in companies, improve trustworthiness, and incentivize reform where needed.

She is also an assistant professor in the Division of Medical Ethics and Department of Population Health at NYU School of Medicine. Before joining NYU's faculty, Dr. Miller was a fellow in Harvard University's Edmond J. Safra Center for Ethics and taught at Duke University's Kenan Institute for Ethics and Fuqua School of Business as the George C. Lamb Regulatory Governance fellow, Fordham University's Graduate School of Business, and Columbia University's Bioethics and Cross Cultural Education Program.

Additionally, Dr. Miller serves on NYU's Pharmacy and Therapeutic Committee (P&T), Stem Cell Research Oversight IRB, and Electronic Medical Records Working Group. She is also a monitor for J&J-NYU's Compassionate-Use Advisory Committee.

an annual statement that will live independently. Companies will be able to say they support it, or don't. That is all we'll ask of them — no money, no sign-off, no statements that they are adherent.

The other component is a research component, and there we will create an integrated, global program of research into industry ethics, voluntarily, but we're hoping that some large pharma companies can deploy internal heads to the program, alongside wonderful academic work such as Dr Miller's. **PV**



Mike Rea

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