

24 Jun 2021 | Analysis

Environmental Sustainability From Bench To Bedside

by Ben Comer

As the COVID-19 crisis recedes, industry leaders are placing a renewed emphasis on environmental sustainability, from API manufacturing and raw material sourcing to package inserts. As NHS England chair Lord Prior said at BIO Digital, "Climate change is going to make COVID look like a picnic in the park."

Sustainability means different things to different people, particularly when you consider the global reach of biopharmaceutical supply chains. Alignment between supplier partners around sustainability metrics is challenging for individual companies, not to mention broad health care industry alignment across sectors, governments and investors.

The principles for sustainable business operations exist, with important contributions from the Pharmaceutical Supply Chain Initiative and the United Nations, for example, but the question for individual companies is one of emphasis, and implementation.

For partners in the supply chain, sustainability is becoming a competitive advantage; as contract development and manufacturing organization sustainability programs mature, they can be expected to "take an active role [in setting sustainability goals] as early as the procurement process," said Seth Levine, senior director, regulatory affairs at Cambrex, a New Jersey-based CDMO, during a Cambrex-led Digital Summit in May. Reducing the carbon footprint of energy-intensive API manufacturing processes, curbing water consumption, and moving to fossil fuel-free steam production were key areas of environmental focus for Cambrex, said Levine.

The good news is that sustainability can be a win/win situation for companies. The World Economic Forum has reported that responsible procurement practices can raise company revenues by between 5% and 20%, reduce supply chain costs from 9% to 16%, and increase brand value by 15 to 30%.



Despite anxiety about added time or costs associated with sustainable environmental practices, "it is actually quite the contrary," said Rohin Mhatre, SVP, product and technical development at Biogen, during a BIO Digital panel titled *Fighting The Climate Crisis Through Supply Chain Sustainability*. "First of all, you're doing a great service to humanity by figuring out how to manage your waste. And it doesn't just go away, you have to pay a lot to get rid of it," said Mhatre. By developing sustainable processes, "your cost of production goes down significantly as well," he said, citing "green chemistry" and sustainable packaging as two focus areas at Biogen.

"We need to find ways to be flexible, to ensure patient and product safety, but at the same time, protect our environment."

Using alternative packaging materials would require a paradigm shift, which needed to include regulators as well, noted Mhatre. Similarly, package inserts need a rethink, said Michelle McMurry-Heath, CEO for BIO, during the panel. "Package inserts are incredibly important to regulators, since they include all of the labeling and [product] directions, all of which is very important," she said. "And yet, the sheer volume of waste [package inserts] create in prescriptions each year is huge. We need to find ways to be flexible, to ensure patient and product safety, but at the same time, protect our environment."

Interestingly, the FDA has attempted – for years – to move package inserts intended for clinicians or pharmacists to an electronic format, instead of paper. However, the US Congress has been successful in preventing this change by disallowing the FDA, via the appropriations process, from converting package inserts from paper to pixels. The reasons cited for blocking this change include patient safety and costs potentially incurred by pharmacists, who would need to find the package insert online. Critics argue that the paper industry, including lobbying efforts by the Pharmaceutical Printed Literature Association, is more concerned about the lost revenue such a digital switch would create. This issue illustrates the challenges involved in shifting any health care-related paradigm, environmental or otherwise. However, public sentiment about the environment, and what needs to be done to protect it, is shifting as well; regulators and government officials will ultimately bend toward the demands of constituent majorities.

Stakeholder Pressure

Investors, too, are increasingly interested in a company's environment and sustainability practices. (Also see "*ESG In 2020: Not A Tick-Box Exercise But A Strategic Opportunity*" - In Vivo, 22 Jan, 2020.) Environmental, Social and Governance (ESG) plans are routinely considered by investors as important metrics for identifying material risks. The "E" in ESG is moving to the



forefront, noted Levine, "due to the significant activities required to achieve continuous environmental improvements, and to reduce a company's impact globally."

"We have received many questions from investors around our sourcing practices," said Matt Shaughnessy, head of operations sustainability, AstraZeneca, during the Cambrex Digital Summit.

Among BIO members, "activist investors are really pushing this topic in a lot of our companies," said McMurry-Health, adding that companies may wake up to a set of demands sooner rather than later, made by "investors around your board tables."

A younger generation of biopharma employees, too, are asking their organizations about commitments to environmental sustainability, and holding them accountable. "It has come up during [employment] interviews, questions like 'What is your commitment?' These are bold questions," said Mhatre. "I'm so glad that there is this awareness in the generation that is coming up."

That pressure is not likely to subside. "If you're currently competitive for STEM talent, in the next 10 to 15 years, you're going to have to have a plan that is compelling to those individuals," said McMurry-Health.

Working Together

In October of 2020, the National Academy of Medicine (NAM) announced plans for a "Grand Challenge on Human Health & Climate Change." The multi-year initiative is focused on three objectives:

- 1. develop a comprehensive and long-term roadmap for transforming systems (including health care);
- 2. mobilize the full spectrum of actors and institutions in the health community; and
- 3. launch a global competition.

The competition aims to "foster innovative interdisciplinary research and actionable solutions at the intersection of climate change and human health."

Victor Dzau, president of the NAM, and a former board member at Genzyme, Medtronic and Alnylam, said on the BIO Digital panel that climate change is associated with approximately 20 million deaths a year, globally, compared with 3.5 million deaths in the last year from COVID-19. He cited Biogen as an example of a biopharma industry leader on climate – the company



"achieved carbon neutrality in 2014," per Mhatre – but noted that there are not yet enough good examples.

Dzau said his hope for the NAM Grand Challenge is bring health care sectors, and regulators, together, and to define metrics and standards with broad applicability. In health care, environmental sustainability needs to follow a path similar to quality standards. "We measure safety and quality, and every hospital, every board has a committee looking at how we are doing. We need [environmental standards] to be measured, and we need incentives for behaviors as they relate to environmentally sensitive issues."

In November, the UK is hosting the UN Climate Change Conference of the Parties (COP26), which will be held in Glasgow, after being postponed in 2020 due to COVID-19. Lord Prior chair of NHS England, said the NHS would be in attendance, with "quite a few major suppliers as well." He described the UK's environmental commitments as "essentially getting rid of the internal combustion engine," or moving away from diesel and petrol. "I'm hoping that we are going to get a very strong agreement at COP26 to get to net zero carbon emissions by 2040, or bring it back earlier than 2050, at any rate."

Lord Prior noted the ease in which companies, and countries, have in the past made long-term commitments on the environment, which was easy to do, since the people making the commitments would not be around to deliver on them. "But we're getting into a time period now of maybe 10 or so years, where people can be really held to account. So, it won't be just empty words in an annual report."

"If you look at the last two decades, there has been SARS, MERS, H1N1, West Nile virus ... they are all zoonotic diseases. As climate changes the environment, you greatly increase the chance of transmission from animal to human."

Relying too heavily on innovation and new technologies to solve the climate crisis was a mistake, said Lord Prior. "I was very struck by John Kerry, [who said in a recent interview] that probably 50% of the innovations that we need to deal with climate change have not yet been invented. That's probably true, but you can't just rely on innovation and science coming to the rescue at the last minute. There are things we can do today, in health systems, in pharma, in biotech, and in all our industries, which will mitigate the size of the problem in years to come," said Lord Prior. "And so the real message from COVID is don't wait until it is too late."



Environmental sustainability and COVID-19 were linked, lab leak theories notwithstanding, noted Dzau. Rising temperatures cause vectors, like mosquitos, to travel farther north and increase vector-borne disease. Additionally, deforestation drives animals into closer contact with humans, and out of their natural habitats. Ebola is a good example. "In West Africa, there is a lot of deforestation, and as a result, bats started bringing zoonotic diseases to humans," said Dzau. "If you look at the last two decades, there has been SARS, MERS, H1N1, West Nile virus ... they are all zoonotic diseases. As climate changes the environment, you greatly increase the chance of transmission from animal to human. That is the key issue, because it can attract the attention and interest of the public, and policymakers, to how urgent this issue is."