2021 Synthetic Biology Update

90 YEARS

QUAKERS
Canadian Friends Service Committee

What is synthetic biology and why care about it?

It's happening right now. Many scientists, technology-enthusiasts, and corporations hope to create novel life forms. They seek to move from evolution through natural selection into a moment of ever more human-designed life.

Combining life sciences, computer science, and engineering, a field sometimes called "synthetic biology" is developing. It uses a suite of powerful techniques with names like "CRISPR."

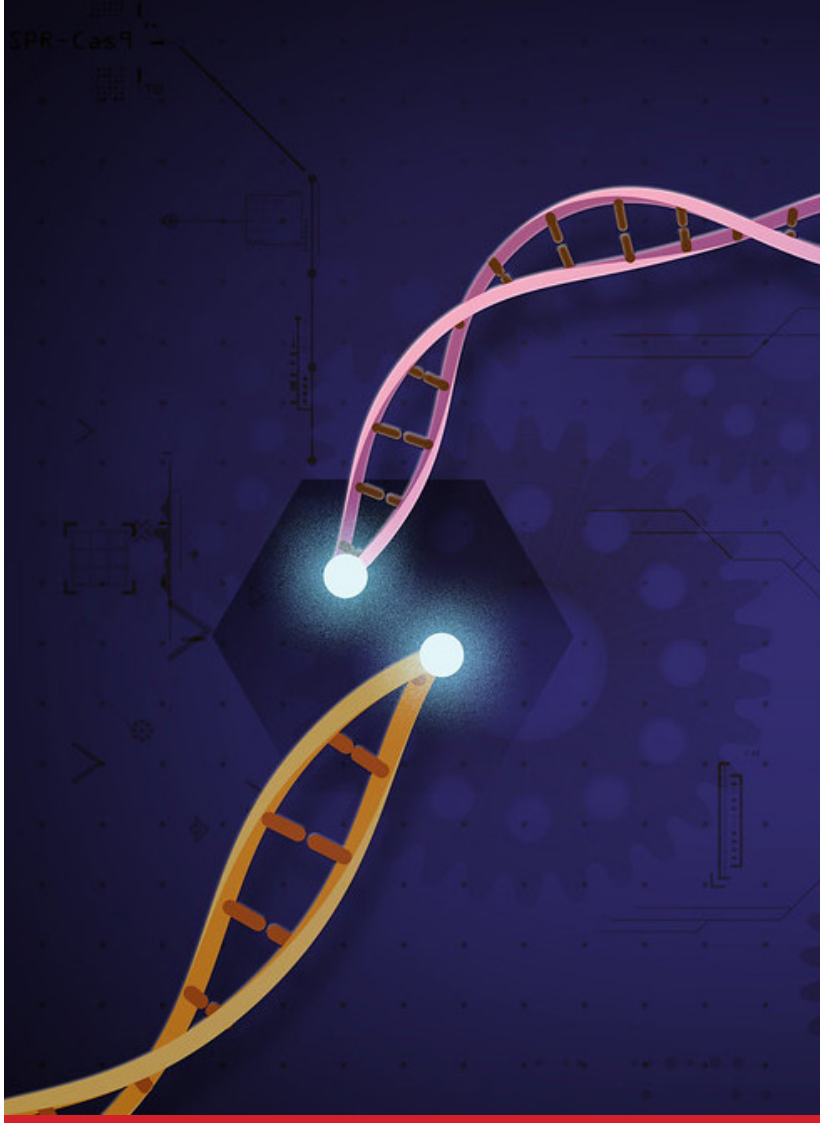
As with other new technologies, there's a lot of hype, many promises, and many perils. Governments have failed to keep pace. The public doesn't provide input into the far-reaching decisions companies make. There's limited regulation.

Canadian Friends Service Committee is the peace and social justice agency of Quakers in Canada. Grounded in our values of peace, integrity, equality, simplicity, and respect for all creation, we are led to pay attention to synthetic biology.

We are particularly interested in the social, ethical, and spiritual implications—both beneficial and harmful—which go well beyond the technology itself. See an overview of our hopes and worries at https://quakerservice.ca/SBIssues

CFSC's specific mandate is listed in the Appendix. It includes sharing easily accessible updates about some of the current applications of synthetic biology techniques. You can find all of our past updates and other information at https://quakerservice.ca/SyntheticBiology

Please share any thoughts or feedback (however brief or detailed): matt@quakerservice.ca



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"I have almost no experience in genetics and have not done hands-on lab work since high school. Still, by following the instructions that came in the box... I was able to create a novel organism... Although it felt a little creepy engineering a drug-resistant strain of E. coli in my kitchen, there was also a definite sense of achievement..."[1]

"If you can repair your future child's myopia with preemptive genetic tinkering, you might also want to increase her I.Q. by a few dozen points. Will it lead to a world... where all the children are above average? Of course not. It will just add genetic manipulation of embryos and child cloning to the means by which affluent, fussy people try to distance themselves from bad luck, disappointment, menial work, death, and poor people."[2]

Synthetic biology is being used in many ways in response to the pandemic.

COVID-19

Our update last year shared how the origins of COVID-19 were the subject of wild conspiracy theories, but that some serious journalists were also speculating about a potential leak from a lab. The *BBC* reports that:

> There have been many well-documented cases of viruses leaking from labs. The first Sars virus, for example, leaked twice from the National Institute of Virology in Beijing in 2004, long after the outbreak had been brought under control. The practice of genetically manipulating viruses is also not new, allowing scientists to make them more infectious or more deadly, so they can assess the threat and, perhaps, develop treatments or vaccines.
>
> And from the moment it was isolated and sequenced, scientists have been struck by the remarkable ability of Sars-Cov-2 to infect humans. The possibility that it acquired that ability as a result of manipulation in a laboratory was taken seriously enough for an influential group of international scientists to address it head on.[3]

This possibility seemed plausible too because the Wuhan Institute of Virology was studying bat coronaviruses. The World Health Organization reports that a lab leak is unlikely, but other theories like the origins of the pandemic in human contact with bats or frozen food also remain unproven. Some continue to argue that the lab leak theory needs more consideration, given the prevalence of serious safety problems at various elite labs working with dangerous viruses. For instance Alison Young writes in *USA Today*:

> As an investigative reporter, I have spent more than a decade revealing shocking safety breaches that officials at laboratories... don't want the public to know about. I have uncovered exotic and deadly bacteria that have hitched rides out of high-security labs on workers' dirty clothing, silently spreading contagion for weeks. I have revealed how spacesuit-like protective gear and tubes carrying safe oxygen to scientists have torn or broken—repeatedly—and high-tech safety systems have failed dramatically. Vials of viruses and bacteria have gone missing...
>
> Without question, the lab-leak theory has been politically and racially weaponized in ugly ways. Nonetheless, that rhetoric needs to be separated from legitimate questions about lab safety that are deserving of investigation.[4]

All we can say, then, is that we still don't know the origin of Sars-Cov-2 and that, as of right now, there's no proof to support the conspiracy theories about it being engineered in a lab. (Hopefully the attention this issue is getting will result in lab safety improvements though. Frighteningly, Young says that "U.S. laboratories reported more than 450 accidents during 2015 through 2019 while experimenting with some of the world's most dangerous pathogens...")

Synthetic biology is being used in many ways in response to the pandemic. Synthetic human lung cells are being grown and infected to understand how the virus acts.[5] Copies of the virus are being synthesized in the lab,[6] and researchers even say that they can rapidly engineer versions of Sars-Cov-2 with desired mutations so that they can be studied. This technique is claimed to be useful for evaluating potential vaccines as well.[7]

"Synthetic attenuated-virus engineering" is being used to create (hopefully) harmless versions of the virus that companies want to turn into vaccines or "inexpensive nose drops for use around the world." Some experts warn, however, that live attenuated viruses are not necessary for Sars-Cov-2 vaccines and add an extra

layer of risk for those who receive them.[8]

Multiple companies are using synthetic biology to develop tests to diagnose COVID-19.[9] The US military's research and development agency DARPA is funding a possible synthetic biology COVID-19 detector that professor Gerri Botte believes could one day work like a carbon monoxide detector in buildings to instantly alert people that COVID-19 is in the air.[10]

There are hopes, also with funding from DARPA, of "reprogramming" human cells so that they "block infection" with COVID-19,[11] and of making synthetic DNA antibodies, which would be much cheaper and faster to manufacture than more established antibody therapies. These synthetic DNA antibodies, "unlike conventional therapeutic antibodies, are administered as genetic blueprints that instruct the patient's body to build its own highly specific antibodies" to fight the virus.[12] This technique is still in its very early stages and no results of human trials have been published.

Other labs are studying and seeking to isolate antibodies from COVID-19 survivors to use them in treatments.[13] Some have even proposed engineering plants to help in diagnosis and vaccine production.[14]

In addition to these many areas of research, various authors have pointed out that the COVID-19 pandemic also needs to draw our attention to the fact that "we continue to overinvest our hope in genetics" and need to focus more resources on equitable social structures that promote health. COVID-19's massively different impacts on different racial groups within the same country, for example, highlight this. These differences aren't due largely to genetics but to "social conditions to which different groups are exposed" including limited access to decent jobs, housing, education, nutrition, clean water and air, contributing to greater exposure to the virus and worse outcomes upon exposure.[15]

In a stark example of the opposite mindset, which rather than focusing on broader social issues searches for quick technological solutions to large complex problems, a paper published in an academic journal[16] argued that to help stop future pandemics, animals should be vaccinated... in the wild. The authors argue for using synthetic biology to engineer a "transmissible" vaccine—a harmless vaccine version of a virus that could self-replicate once released and thus have the potential for indefinite transmission between animals, vaccinating them all.

What could go wrong? A letter to the editor in response, itself written by synthetic biologists, says:

> Any self-replicating agent released into the wild will be selected for enhanced transmission, underscoring the unpredictable evolutionary risks inherent to the engineering and release of transmissible viruses. Mutations or recombination events with wild viruses may lead to an increase in pathogenicity or host range expansion, including to domesticated animals or humans.

So the harmless vaccine could become deadly over time, and wind up being transmitted to humans. The authors of the paper do propose safety measures, but the response letter explains that it is already known that these are likely to fail: "conceptually similar safeguards have been tested extensively in laboratory bacteria and viruses, both of which lead to reliable evolutionary escape at relevant population sizes."

The letter to the editor also notes, "In addition to these troubling safety concerns, the development of transmissible vaccines will incur grave biosecurity risks due to the dual-use potential of the insights, tools and experience gained through such work." Knowledge gained through research into vaccines that spread in the wild could be used to spread a new deadly virus instead.

The response letter does still agree with the idea of vaccinating animals in the wild though. It simply endorses a different method: "non-contagious vaccines applied to animals and spread through behaviour such as grooming."[17]

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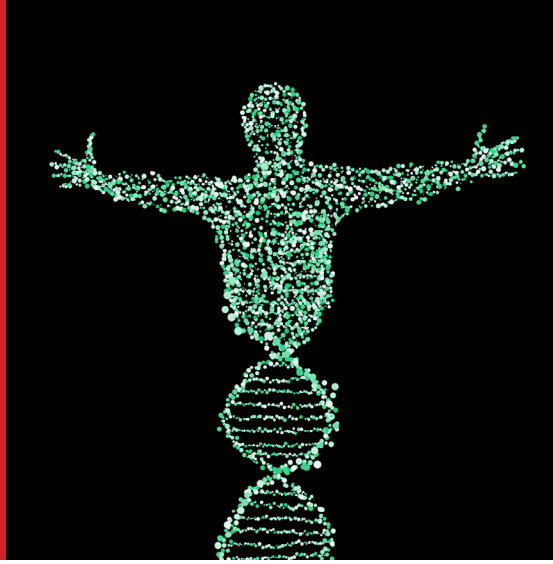


Gene drives

The paper on contagious vaccines is far from the only one advocating for interventions in wild animal populations using synthetic biology. A number of articles this past year continued to advance the argument that humans have destroyed most ecosystems so thoroughly that the best hope for salvaging some of them is to try to undo past human-caused harms through newer higher-tech interventions: synthetic "gene drives."

Readers of our updates know that a gene drive would be, if it worked, one of the most powerful applications of synthetic biology. It would force a new trait to be inherited by an entire population, or even a whole species, in the wild. Since 2016, CFSC has joined groups from around the world in calling for a moratorium on gene drive research until meaningful regulation exists (regulating such a powerful biotechnology seems extremely challenging).[18]

This call has been unsuccessful, and research continues, with the hopes of using gene drives to crash mosquito populations or kill off invasive species like toads and mice. Here's one articulation of that logic from a 2021 article in *The New Yorker*: "Invasive species alter the environment by adding entire creatures that don't belong. Genetic engineers, by contrast, just alter a few stretches of DNA here and there.... Rejecting gene editing as unnatural isn't, at this point, going to bring nature back."[19]

Gene drive research continues to find unexpected results, highlighting how much is still uncertain about its potential viability and impacts.[20] Essential questions remain about the need for free, prior, and informed consent of the people whose environments may be impacted by a gene drive. These issues are not touched on by framing the discussion as all about altering a few stretches of DNA in an ecosystem.

As with infectious vaccines, any research done on gene drives is dual-use. If this technology works to crash a mosquito population then as we've reported previously, DARPA has expressed the possibility that it might be used as a weapon to destroy a food crop and cause mass starvation. Most recently a paper from senior faculty at the US military's West Point Academy, all of whom are positive about the potential benefits of synthetic biology, shares grave concerns that the ability to create a bioweapon is becoming increasingly attainable as the funding and specialized expertise required decreases.[21] Thus, for good reason, gene drives continue to be hugely controversial. Yet no meaningful regulatory system exists, and the world depends largely on scientists and corporations to self-regulate.

Editing humans

If you read any science stories over the past year chances are high that you read about CRISPR. When the 2020 Nobel Prize was given out for discovery of the technique, media could not have been more positive. Here's a typical description from Nobel Prize winner Jennifer Doudna:

> With CRISPR enzymes, we can cut DNA at precise locations, using specifically designed proteins, and insert or delete pieces of DNA to correct mutations. As we deepen our understanding of the human genome and genetic disorders, patients with previously intractable diseases, such as sickle-cell disease and cancer, will benefit more widely from CRISPR-based therapies that are rapidly moving from the lab to the clinic. [22]

Again this year multiple studies raised questions and scientific debate about how precise CRISPR is. "'There's no sugarcoating this,' says Fyodor Urnov, a gene-editing expert and professor of molecular and cell biology at the University of California, Berkeley. 'This is a restraining order for all genome editors to stay the living daylights away from embryo editing.'" Urnov was describing the results of a study conducted on human embryos (only grown for two weeks in the lab and then destroyed) that had their genes edited. About half of the edited embryos showed major unintended edits, the sort that might increase the risk of birth defects and cancer.[23]

In different experiments a new tool was used to discover that CRISPR edits do more damage to nearby DNA than was expected. Dr. Eric Kmiec, principle author of the study, said, "We've developed a new process for rapidly screening all of the edits made by CRISPR, and it shows there may be many more unintended changes to DNA around the site of a CRISPR repair than previously thought." Knowing what the consequences of these changes are will require further study.[24]

Research in mice found large numbers of unwanted duplications while making CRISPR edits, and troublingly, these duplications had gone undetected with common methods. "Without using techniques suitable to detecting such duplications, researchers may not be realizing" that the problem even happened.[25]

Another study found that, to the researchers' surprise, damaged DNA can still produce functional proteins. This is significant because it means that dozens or hundreds of experiments that assumed they had successfully used CRISPR to remove proteins but didn't validate that this was the case could have published results that are incorrect or misleading.[26]

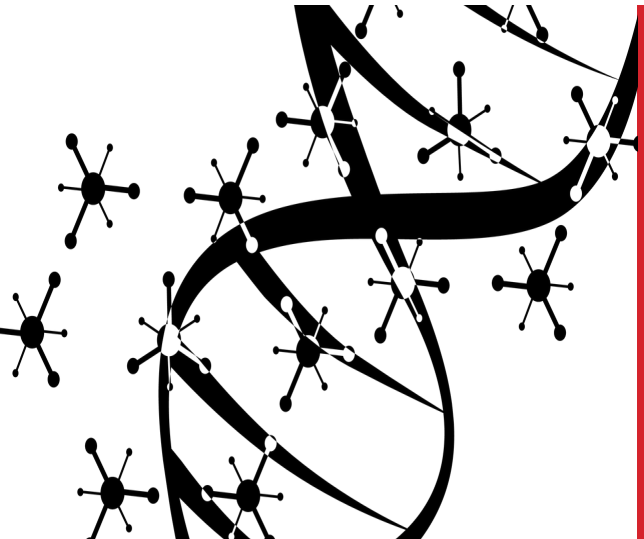
In 2020 a gene therapy attempting to treat a rare neuromuscular disease tragically seems to have led to the death of three children involved in the trial,[27] and already in 2021 a gene therapy attempting to treat sickle-cell disease was put on hold when two patients developed cancer.[28] These cases are still being studied so there is not yet a conclusive understanding of if or how the gene therapy treatments contributed to these deaths and cancers.

As we reported last year, there also remains the potentially more major fact that some models of genetics suggest that even intended changes to a gene can lead to unexpected results for people. That's because of how many genes (perhaps tens of thousands) each contribute in small ways to many different human traits. These models throw into question the metaphor (often used in in discussions about synthetic biology) of the cell being like a machine with parts that can be precisely tinkered with, yielding predictable results.

Most synthetic biologists remain confident that these issues can be overcome. Taken together, in addition to promises of fixes for health problems, recent findings have raised further concerns about the possible harms to gene edited humans.

Another instance of the type of research that raises ethical questions came when synthetic biologists said they had created mice that had more than 4% human DNA, "the highest level of human cells in an animal yet."[29]

While discussions about the feasibility and morality of editing people and human-animal chimeras continue[30] (82% of people surveyed in multiple countries say it would be wrong to edit an unborn baby to improve its intelligence, but most support edits if they could address a serious disease the baby would have at birth[31]) there is still no meaningful international framework in place to guide or limit this work.



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Medicine

Geneticists are finding that common diseases like diabetes are much more complex than they once hoped. But,

> In 2016, the year [the US National Health Institute] launched a major new genetics-focused research initiative, it spent well over half of its $26 billion budget… on investigations that could be linked to search terms that include gene, genome, stem cells or regenerative medicine. That major new program—called All of Us—aims to tailor medical care to the genomes of individuals, much as tailors create clothes to fit their customers. To achieve that end, NIH is seeking to enroll 1 million people in the program…[32]

Whether or not this vast investment can ever deliver the much-touted medical benefits remains very unclear.

If diabetes is complex, how about mental health? Yet a biotech company says it's using artificial intelligence (AI) to study mental illnesses and develop novel pharmaceutical drugs. They claim they will be able to use big data to visualize the complete activity of the compounds they test and then "specially tailor drugs to target specific disease pathways related to mental health—all while mitigating off-target interactions." Naheed Kurji explained, "Our vision is to spark a new era of drug discovery centred on a robust computation-centric approach."[33]

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The US military is funding researchers trying to alter the bacteria living on soldiers' skin to repel mosquitoes. The project hopes that a single application of synthetic biology bacteria would be able to change the smell that soldiers' skin gives off, possibly keeping mosquitoes (and thus mosquito-borne illnesses) away for a long period of time. However scientists are unclear exactly what attracts or repels different breeds of mosquitoes to humans. Furthermore it's unclear exactly what all of the impacts of changing the skin microbiome would be, or even how humans get their skin microbiomes, which appear to be "the unique product of many overlapping factors: gender, genetics, occupation, grooming habits, neighborhood, etc. Experts think these differences account for why mosquitos are more attracted to some people than others…"[34]

Biotechnology can be overhyped and later turn out to be much less precise or useful than claimed, and the same is true of other new technologies like AI.

Food and other applications

A company is claiming to have engineered "breast milk" by making stem cells lactate. They hope that this will soon allow them to win parents away from buying baby formula. The claim is that although this synthetic biology "breast milk" will be more expensive, it will also be more nutritious.[35]

Others in the field continue to talk about "gene editing to modify livestock and agricultural products" as having the potential to create "disease resistant domesticated plants and animals" and also "more productive varieties... that can survive and thrive in unusual and changing climates." There are discussions about using big data and AI to understand climate and ecological changes and engineer novel animals and plants to meet human needs.[36]

Biotechnology can be overhyped and later turn out to be much less precise or useful than claimed, and the same is true of other new technologies like AI. "AI moves quickly from research labs to real-world applications, with direct impact on people's lives. But machine-learning models that work well in the lab can fail in the wild—with potentially dangerous consequences."[37] The greater the number of new and poorly understood technologies introduced into attempts to solve a problem, the more likely it seems that major errors will occur due to uncertainties, unknowns, and ambiguity in defining and understanding that problem.

In Mexico's Yucatan Peninsula, genes from edited cotton plants have escaped and traveled over 2,000 kilometres. A research team that documented this by studying a small number of wild plants was able, for the first time, to see how novel genes led to unexpected and demonstrable changes to a wild ecosystem.

> One type of escaped gene makes wild cotton exude less nectar. With no means to attract defensive ants that protect it from plant eaters, the cotton is devoured. Another escaped gene makes the wild cotton produce excess nectar, enticing a lot of ants that might keep other insects, including pollinators, at bay...

Evolutionary biologist Norman Ellstrand explains that, "It's the first case that really suggests that a whole ecosystem can be disrupted" when transgenes escape into a wild population. Most studies of genetically altered plants are done under carefully controlled conditions and don't even try to look at potential consequences if genes are transferred to wild populations.[38]

With the help of synthetic biology techniques, new pesticides are being developed to overcome insect resistance to current pesticides.

> Insects that are exposed to it—either by eating crops sprayed with the substance or by landing on a crop and absorbing it through their bodies—would be genetically modified right there in the field. The pesticide would trigger a process inside the insects' cells to switch off or 'silence' genes that are essential for survival—like those needed

to make new, healthy cells—thus killing them.

But critics highlight potential problems, including that the genetic modifications might be passed on to future generations of insects, that the pesticide might kill a wide range of "desirable" insects such as pollinators, and that potential impacts on human health have not been researched sufficiently.[39]

Even as industry continues to argue that genetically edited foods are both novel enough to be patentable and also indistinguishable from non-edited foods (so as not to require regulation), a collection of nonprofits came out with a new technique that a study says is able to reliably tell if a canola crop has been gene edited.[40]

COVID-19 synthetic biology conspiracy theories seem to lack any basis in reality. But this can't be said for every conspiracy linked to biotechnology. The company Monsanto, famous for its use of biotechnology in food, had to release many internal documents in a court case. In doing so it exposed that it had run a large-scale operation to monitor and seek to discredit journalists and activists. The company apparently thought of its operation as akin to what government intelligence agencies use to track violent extremism.

The Guardian reviewed the records showing Monsanto writing talking points for third parties to use to attack journalist Carey Gillam, who was investigating the health hazards of the company's herbicide Roundup. *The Guardian* also reports, "Monsanto officials were repeatedly worried about the release of documents on their financial relationships with scientists that could support the allegations they were 'covering up unflattering research.'"[41] Revelations like these make it reasonable to wonder: how common or uncommon are such practices in shaping public opinion about synthetic biology and older genetically modified organisms? And do those opposed to biotechnology also use these sorts of manipulative techniques?

Scientists continue attempts to use DNA to store data. This year they encoded the words "Hello world!" into the DNA of a living bacteria. This was the first time that data had been encoded directly from a computer into living cells. Much larger amounts of data have been successfully encoded into nonliving DNA that was synthesized in a lab.[42]

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Appendix

In 2014 Canadian Yearly Meeting, the national body of Quakers in Canada, asked Canadian Friends Service Committee, the peace and social justice agency of Quakers in Canada, to work on synthetic biology in the following ways:

1. By affirming the seven principles identified in *Principles for the Oversight of Synthetic Biology*, a document that makes many important recommendations, and supporting attempts to implement the seven principles:

    i. Employ the precautionary principle;

    ii. Require mandatory synthetic biology-specific regulations;

    iii. Protect public health and worker safety;

    iv. Protect the environment;

    v. Guarantee the right-to-know and democratic participation;

    vi. Require corporate accountability and manufacturer liability; and

    vii. Protect economic and environmental justice.

2. By providing Canadian Quakers and the general public with an annual, easily understandable update on synthetic biology;

3. By finding opportunities to link with other faith and community groups, and with Indigenous peoples, to share insights and discernment about synthetic biology; and

4. By engaging with other faith groups and interested parties (including organizations involved in research and/or manufacture in synthetic biology), hold and/or participate in conferences that address ethical, spiritual, social, and economic aspects of synthetic biology.

In 2014 Canadian Yearly Meeting, the national body of Quakers in Canada, asked Canadian Friends Service Committee to work on synthetic biology.

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