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New Standards for Gene Synthesis Screening

BY GREGORY E. KAEBNICK

How should we think about risk when evaluating emerging biotechnologies? That question is at the core of a long-running debate over the merits of the “precautionary principle,” which is variously interpreted but is usually said to concern the burden of proof. The principle says, roughly, that one may not move forward with a technology until the risks are identified and shown to be manageable. This is the only way, proponents of the principle say, to avoid the environmental damage and public health problems that new technologies sometimes wreak. Critics say the principle would lead to paralysis, as one can never know the full results of one’s actions before acting.

But almost certainly this is a false dichotomy, as a current dispute over the newly emerging field known as synthetic biology helps show.

What defines synthetic biology is a goal: the development of new strategies and tools for engineering organisms—microbes, mainly—to do things no naturally occurring organisms can do. Synthetic biology lies at the confluence of several existing biotechnologies, and particularly of vastly improved techniques for chemically synthesizing DNA sequences. To assemble DNA, researchers can now often just purchase strings over the Internet from commercial “gene synthesis” companies.

The potential benefit is enormous—for starters, better ways of producing drugs, fuels, and many other materials. Prominent concerns include safety and deliberate misuse. Scientists have recreated polio and Spanish flu in the lab and will eventually be able to make smallpox and other more complex pathogens. Someday, conceivably, these pathogens could be modified to be more destructive and altogether new pathogens could be designed. Might rogue states or terrorists someday be able to do these things?

One strategy for avoiding harmful uses is for gene synthesis companies to screen the orders they receive and avoid selling potentially dangerous genes to dangerous customers. The custom among these companies has been to compare customer-submitted sequences against Genbank, a federally maintained database of known genes, look for the closest match, and determine what functions the match codes for. If

the functions are dangerous, the company can examine the customer more closely before filling the order.

Over the last year, the International Association for Synthetic Biology, a trade group, has been negotiating a code of conduct that would make these practices standard across the industry, and a final version of the code was approved in November. But this is where the dispute arose. The IASB process requires human screeners and is expensive. Last summer, two companies (DNA2.0 and Geneart) proposed an alternative approach that dispenses with humans and relies on automated screening against a set list of genes known to pose threats. The alternative would be faster and cheaper, but

almost certainly less thorough. “In order to match the performance of human screeners,” wrote Stephen M. Maurer, director of the Information Technology and Homeland Security Project at the University of California at Berkeley, in a recent essay in *Bioethics Forum*, “it would have to

contain a detailed threat assessment for every gene in Genbank. I do not know a single knowledgeable expert who believes that such a list can be built any time soon.”¹

We do not need to endorse the precautionary principle to see the benefit of taking extra precautions in gene synthesis screening. Though the risks are uncertain, the facts on the ground are plain enough to make a general algorithm for assessing risk and benefit unnecessary. Indeed, the debate about the precautionary principle may be actively unhelpful. It easily degenerates into all or none options: should we stand in the way, or wave things through as fast as possible? In fact, as the negotiations over DNA screening make clear, one could even be staunchly in favor of a new technology—the members of IASB are—while advocating extra precautions in introducing it. Indeed, a precautionary stance here might help promote the technology by making acceptance of it easier.

In December, the U.S. government proposed draft guidelines for DNA screening by gene synthesis companies. Unfortunately, the draft endorses a version of the faster but less thorough approach. The comment period for the draft ends on January 26.

1. S.M. Maurer, “Synthetic Biology Marketplace: Screening Out Terrorists,” *Bioethics Forum*, <http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=4158>.