

La *synthetic biology* e le sue innovative applicazioni in campo farmaceutico: prospettive, rischi e responsabilità civile

AGNESE QUERCI

Synthetic Biology and its Innovative Applications within the Pharmaceutical Field: Perspectives, Risks, and Liability

Abstract: Synthetic biology has interesting developments in the pharmaceutical field, because it can allow us to produce more quickly existing drugs (such as vaccines and drugs against malaria) and to cure diseases which were incurable in the past (for example, HIV). At the same time, it creates great doubts, both in the field of ethics (because of the use of the DNA in the laboratory to create new living organisms), and from the point of view of safety (because the new techniques have not yet been sufficiently tested), even on a global level (issues related to bioterrorism and bio-security). Faced with these problems, there are two main questions that this paper tries to solve: a) if there are legal rules in force which can regulate the new products, or whether we need to introduce new rules or regulatory bodies or soft law instruments; b) what role can civil liability and the development risk defense play in the case of damage caused by the new pharmaceutical products.

Keywords: Synthetic biology, Drugs, Risks, Liability.