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## Shift from biologics to biosimilars: Ethical and legal challenges

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Biologics is considered one of the most significant biomedical developments of the past few decades because of its therapeutic benefits. A biosimilar is a copy of a biologic medicine that is similar, but not identical, to the original medicine. Biologics include a wide range of products such as vaccines, blood and blood components, allergenic etc. In some areas, such as rheumatology, many clinicians have endorsed switches to biosimilars. One difficult challenge is about the robustness of certain jurisdictions' approval processes and the potential for differential effects on a patient-to-patient basis. Physicians and other health care professionals are often faced with the difficult decisions regarding competing obligations to patients and to the greater health care system. The existing legal and ethical framework largely directs physicians to focus on the interests of the patient, making physician–patient relationship fiduciary in nature. Physicians are bound by the issue of ethics and practice. Switching from biologics to biosimilars for cost containment purposes can be difficult due to the lack of any statement in the relevant professional codes and standards. Governments implement switches from biologics to biosimilars because of its cost effectiveness. The requirement for extensive testing of biosimilars prior to its approval incurs a toll that has not been well explored or characterized. The toll includes an unmeasured opportunity cost, in that enrolling subjects with conditions on trials of biosimilars would likely rob trials of innovative treatments for the same condition of potential human volunteers. If biosimilars are to live up to the expectations they must do more than simply look for a marginal cost savings.

### Biography

Sunil John is an Associate Professor at the School of Law, Christ University. He has done his PhD in Natural Law theory of St. Thomas Aquinas. He specializes in International Law and Jurisprudence and takes a keen interest in medical jurisprudence and ethics.

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