



# GOVERNANCE

BASEL INSTITUTE ON GOVERNANCE

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## **A Critical Appraisal of the Regulatory Framework of the Pharmaceutical Industry (ABSTRACT)**

**Professor John Abraham, Sociology Dept. Sussex University, UK**

Regulation is not an end in itself. It should be pursued in relation to some wider objectives. Industry self-regulation and state regulation of industry need to be set against those objectives. The intelligibility of the existence of the pharmaceutical industry is that it should produce products that benefit public health. This presentation will examine how well the regulatory framework of the pharmaceutical industry meets that objective. In particular, it will discuss the relationship between the industry and regulatory agencies; the production of drug testing standards; the public accountability and transparency of the industry; and the direction of drug development and innovation. It is argued that self-regulation is not an alternative to regulation by the state. Rather, self-regulation is likely to be most effective in the context of stringent, independent and publicly accountable regulation by government. Under these circumstances, the pharmaceutical industry would be encouraged to develop better systems of self-audit, self-criticism and self-reflection.