The effect on pharmaceutical research

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To help assure that the benefit–risk ratio in the assessment of drugs is a favourable one, most governments have increasingly regulated the pharmaceutical industry. We have arrived at the point where we must examine some of the costs of this regulatory environment. For a long time the industry enjoyed a relatively supportive public. The great medical advances of the 1940s and the 1950s increased public expectations of the wonders that could be wrought by new drug therapies and took attention away from associated risks. Then, in the 1960s, fed by political cynicism, at least in the United States, and ignited by the thalidomide tragedy, public suspicion that the industry’s profit motive was contrary to the public’s interest in safety and effectiveness began to gain momentum. The current adverse regulatory environment is generally a product of this 20-year era of public disillusionment with ‘riskless’ drugs and the social role of big business.

In one regard I think we can welcome this change in public opinion about drugs. There is no drug that is completely safe. There are always medical risks associated with drug therapy that need to be weighed against the benefits. The public is now beginning to gain some appreciation for what successful pharmaceutical firms for many years have been weighing, in what I feel to be a very reasonable fashion, before they brought a drug to market. But in another regard, there are disturbing signs that the public cynicism embodied in our current regulatory environment is not serving the public interest in several respects. We do not question the objective of government regulation intended to assure the public of safe and effective drugs. We are concerned, however, that regulation is causing much unnecessary expense and significant time delays. The real penalty that ensues is falling on the public. The sick are being denied new therapeutic agents. New products that reduce the cost of health
care by diminishing the need for hospital stays are being delayed, and financial resources are not being applied to efforts that will increase our economy’s productivity and reduce inflation.

A first step toward eliminating these unnecessary costs to the public involves clarifying the costs and benefits of our current regulatory environment. If we are successful in this endeavour, we shall have a basis on which to help build a new social consensus on the drug safety issue that incorporates an understanding of these costs. The time is ripe. Evolving concepts of safety associated with improvements in technology and growing concern with the long-term effects of drug therapies, as well as growing recognition of the impact of regulation, are increasing the need for a new social consensus on drug safety.

![Figure 6.1](image.png)

**Figure 6.1** The worsening trend in IND times for US self-originated NCEs. From Wardell, W.² based on a sample of 39 self-originated NCEs

In the interest of helping to ensure that this new consensus is based on an understanding of the costs of our current regulatory environment, I shall devote the rest of the paper to exploring one area, namely pharmaceutical R & D, where we are only now beginning to realize the size and scope of the impact of current regulation. Academic and industry researchers have been making significant progress in understanding the compliance costs associated with such regulations, i.e. the costs to carry out regulatory requirements, and in understanding the full scope of what economists call the secondary or indirect effects of regulation on pharmaceutical R & D.

I shall speak in large part from a US perspective, given that is what I know best, but my comments will be found to be relevant because of the similarity of