Can Regulation co-exist with Innovation?

A recent article in The Atlantic Magazine provides an interesting perspective on the relationship between regulation and innovation *. The question! "can regulation (if excessive) and innovation co-exist"? History may suggest not.

In the mid-1200's an enlightened Teutonic prince, Henry The Lion granted a Charter to the city of Lubeck that encompassed an autonomous City Council, light regulation, fair laws and exemption from customs and duties. The feudal hierarchical system was abolished. As a consequence merchants flocked from all parts to set up shop in Lubeck. Trade and commerce flourished. Other Baltic cities copied the Lubeck template. The Hanseatic League developed, a loose economic alliance that lasted several centuries until unification programs across Europe (the "mergers" of their time?) subsumed such places into "national" entities (and we all know what happened later).

Hong Kong is a more recent example. This too had a charter imposed by the British after takeover. Regulation was light, as were taxes. Hong Kong became a byword for commercial vitality and a place to do business. Mainland China eventually took note and set up copycat economic zones that catalysed the explosion of economic growth and prosperity that China has experienced over the past two decades. This contrasts with the top-down monolithic "command and control" model of The Soviet Union that collapsed as an economic engine in the short time (in historical terms) of about 75 years.

What all this got to do with innovation in the Pharma Industry? Well, nobody can dispute that the industry is highly regulated (possibly overly so?). National and transnational regulatory agencies have vast organizations that review, inspect, adjudicate, monitor and "advise" virtually all aspects of Pharmaceutical R&D, manufacture, promotion and *modi operandi*. Large Pharma organisations also have large groups in place to cope with the requirements (evidenced by the growth of Regulatory Affairs and "Quality" functions in the past decade). The poor Works Director or Head of Quality is piggy-in-the middle. Even R&D scientists spend considerable periods of time attending to the bureaucratic requirements of GCP, GLP and GMP, like writing and becoming familiar with operating procedures (and amending them), generating, reviewing and assembling data that add little value (but is required by Agencies) and continually trying to ensure that all parts of far flung organizations operate a "single quality standard".

What is all this doing to innovation? Can such a culture explain the dearth of new medicines, despite our ever-increasing understanding of molecular biology, the plethora of good targets and the continuing need for new products as requirements evolve with demographics and markets? All the innovation seems to be with the smaller nimble organizations but they are rarely resourced to carry out late-Phase development. They have little option but to sell to the "big boys" when proof of concept or other milestone is met. Big Pharma however seems to continue to be fixated with mergers, takeovers and economies-of-scale policies that result in never-ending bureaucratic activity so that "everybody operates to a single quality standard".

Gibbon's masterpiece "The Decline and Fall of the Roman Empire" attributed its demise, not to the barbarians at the gate but to an over-extended bureaucracy, asphyxiated and drowning in processes, information gathering and reporting.

Does that strike a chord?

Do we need a modern Prince Henry?

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* http://www.theatlantic.com/magazine/archive/2010/07/the-politically-incorrect-guide-to-ending-poverty/8134/