

Trimanos



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November 23, 2004

Trimanos Newsletter

These are sobering moments for the pharmaceutical industry. With the withdrawal of Vioxx, not just a single "blockbuster" but a whole class of drug is at risk. With the testimony to Congress of Dr. David Graham about failures inside the Food and Drug Administration (FDA), the credibility of perhaps the single most powerful regulatory body in the world is called even more deeply into question. With the questioning by Elliott Spitzer, New York Attorney General of the validity and integrity of the publication process for clinical trial data another key plank is knocked out from the ethical pharmaceutical industry platform.

The CEO of AstraZeneca, Sir Tom McKillop put it this way: "If the perception is that we are only interested in making money, then we have got to take that on board. Companies have to be increasingly transparent in how they deal with their social obligations, how they deal with the reporting of trials" (Interview, Sunday Times, November 21, 2004, Section 3, Business, p.1)

The risk to the wider clinical research process is that it starts to suffer the same public scepticism that has hobbled nuclear power and biotechnology, to the extent that an activity which is essential to all of us may get stopped in its tracks, ironically by the very precautionary principle on which it rests. We all have a stake in quickly finding a way for the industry to operate that is accountable and transparent

In 1998 I assisted the newly merged PriceWaterhouseCoopers consulting business with a publication entitled Pharma 2005: An industrial revolution in R&D. PwC was bold enough to quote me directly in Section 9, p.20, which I also largely wrote: "The old way of doing R&D is about to implode". Well, implode it has. But is this just a failure of an industry? No. This failure is one both society and government have had a hand in creating. By consent, not just default, the fundamental equilibrium between commerce, social good and scientific progress has been disturbed. We all urgently need to find a way forward since there is no turning back to the model that just broke.

In a process, such as drug development, that can take 10-15 years to accomplish implosions follow a pattern. They start imperceptibly, and for the untrained eye are not happening at all; then they reach a point of disequilibrium and speed up. Perhaps, like the airlines, the industry as a whole is about to witness the fact that for all the profits of the past decades, it will end up as a zero sum game. This scenario may be avoidable if the leadership in the industry commits to a new way of doing business; and the extent of the damage now being done may just create the conditions for such a change, since there are no obvious winners from a scenario based on the status quo.

The real theme of my 1998 writing was not doom and gloom, but to advocate the need for rebuilding a new social contract within which clinical research, and the pharmaceutical industry, can successfully operate. This new contract has to eliminate the inherent conflicts of interest which I believe are one of the systemic causes of today's failures. These conflicts stem from the fact that as patients we wanted the cheapest possible, best quality medicines, while as pensioners we need profitable pharmaceutical companies to maintain their dividend payments into our pension funds, or private equity accounts. Working in clinical research we of course want to be well remunerated, but our remuneration is a cost driver which the end consumer (which may well be ourselves and our families) cannot afford. Too much emphasis has been paid to quarterly returns and satisfying the City and Wall Street; not enough attention has been paid to the underlying purpose of research which is the advancement of understanding and best practice in the prevention and management of disease, the promotion of health and well-being and the ethical practice of the science and art of medicine.

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The incentive for change for all parties is that a socially responsive, needs- rather than money-driven research process actually ends up in a commercially more sustainable business sector than is currently the case. Will the researchers respond?

I believe they will. From 1999-2002 I led the efforts of the Association of Clinical Research Professionals to extend its certification offering from Clinical Research Coordinators (CRCs) and Clinical Research Associates/ Monitors (CRAs) to Investigators. Against the predictions of many, including many ACRP leaders, the move was a success, especially in areas of the world relatively new to clinical research.

In the Investigator training programs the ACRP team developed at that time were key elements exploring the ethical context for clinical research, both in terms of key issues for physicians, such as the Declaration of Helsinki approach to placebo trials, as well as the relationship between research and society. It was obvious to me from the attention given by participants in our training to these issues, and the very real commitment it elicited from them to improve the current situation that our current dilemma was far from insoluble. But the problem will not fix itself. We need a new policy, not just a new practice.

Perhaps to the shame of the developed world, it has been developing countries, many in sub-Saharan Africa dealing with the AIDS epidemic that have taken the lead in redefining the policy terms under which the new social contract needs to be written. We have much to learn from this initiative.

Why this in the form of a Newsletter about Trimanos? For the simple reason that Trimanos as a system has been developed since early 2003 both from the background of impending crisis, but equally from a deep conviction that clinical research is as vital now as ever. Drug development, and the pursuit of new therapies, can find a sustainable balance between profit and public good; but we are all stakeholders in the outcome, and we all need to share responsibility for the safe and effective conduct of the process.

In the spirit of financial transparency advocated by Tom McKillop, Trimanos has been fully funded by those who believe in it, out of their own pockets and resources.

Julian Hilton
Chairman