

RESPONSE TO THE EUROPEAN COMMISSION'S 'LEGAL PROPOSALS ON INFORMATION TO PATIENTS'

Dear Sirs,

I feel unable to respond to your consultation on 'patient information' on the point-by-point basis proposed. But I do wish to register the strongest objections to your plans, not least for the reasons explained in the statement you have received from the consortium of eleven organisations, led by ISDB, MiEF, HAI and AIM, also in papers from the Picker Institute and others.

From a health perspective, the proposal to expose people to more and more disease awareness messages from pharmaceutical companies seems destitute. It is especially unacceptable that DG Enterprise & Industry should be trying to legalise direct-to-consumer promotion of prescription drugs, yet again by dressing it up as a proposal to liberate consumers with better drug information.

The Commission's proposals stand for principles that, after 30 years of professional engagement in this field, I have learned to abhor. An abbreviated Curriculum Vitae is attached at Appendix Two.

As a prescription for health, this consultation exercise seems essentially cynical. The main objective of DG Enterprise and Industry (DGEI) is to promote European trade and economic development. That is a legitimate interest in its own right, but it presents grotesque conflicts of interest when it comes to shaping health policy – and these proposals exemplify them. DGEI greatly over-estimates the support they deserve, no doubt partly in the expectation of strong backing from the industry-funded patient groups that it has traditionally promoted and preferred.

The consultation document lacks any coherent health impact assessment. Its proposals further blur the distinction between high and low quality information, and take no account of the

health impact of the far greater *quantities* of partial information to which people will now be exposed. That is a crucial omission.

Professional judgment underpins my fear that the longer-term impact of these proposals will be to damage health and beckon *Pharmageddon*. See Appendix One. It is of great concern that the European Commission should so vigorously and uncritically promote the cause of an industry whose behaviour is routinely seductive, deceptive, manipulative and grasping, and whose output of useful new drugs is low and in decline.

The activities of the leading pharmaceutical companies – all deeply engaged with DGEI – mainly distract from the health problems we face. Medicinal drugs are of course sometimes extremely valuable – but can only ever be a small part of the effective solutions we need. Real health grows from the roots up, not from cabals down.

Europeans need to take personal responsibility for their own health, and to understand how much it depends on the health of local and global community. DG Enterprise & Industry completely fails to appreciate that you paralyse the healthy human response, once people come to believe that their genes, body chemistry, and social and cosmetic camouflage are key to developing health and well-being. These proposals take absurdly for granted the benefits of technological and medical intervention

People can never take responsibility for health if bombarded with disease awareness propositions – relentless reminders of their vulnerability, with the promise of drug solutions always to hand. This drive to medicalisation not only makes people feel resourceless and ill; it also threatens the very existence of national health services, by creating unsustainable demand.

What do these proposals have to offer in terms of promoting clear and general understanding of the real benefits, risks and harms that come from pharmaceutical interventions? Possibly one step forward; probably three or more steps back.

Health is basically to do with eating sensibility and sufficiently, taking enough exercise, avoiding toxic exposures, and social security and justice. Disease awareness propaganda diminishes these imperatives and makes the situation worse. Medicines have their place, but it is folly to promote them as if they were the bedrock of health development and the key to maintaining good enough levels of personal confidence, social equilibrium and mental and physical health.

These dismal and potentially dangerous proposals from DG Enterprise seem to me a portent of the health chaos that the European leadership on medicines might first precipitate and then hopelessly fail to contain.

I would be happy to further explain and justify these observations, if required.

Yours faithfully

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Appendix One: *Pharmageddon?*

Pharmageddon has been defined as, "the prospect of a world in which medicines and medicine produce more ill-health than health, and when medical progress does more harm than good". We see the need to investigate and explore that risk and to identify the factors and features that describe it.

Pharmageddon embraces the arguments of Ivan Illich (1976) but extends his focus. He warned of the risks of medicalisation, the generally dehumanising and damaging effects of professional interventions: "*the medical establishment has become a major threat to health*". Beyond direct drug injury (clinical iatrogenesis), he was concerned about the ill-effects of medicine on culture and community, "*the paralysis of healthy responses to suffering, impairment and death*" that resulted from "*the expropriation of health*".

But since Illich wrote, the whole shape of medicine has changed – both the knowledge base and its applications - and the pharmaceutical industry has come to dominate the medical establishment and the thrust and ethos of drug research, regulation, prescribing, availability and use.

The values of the market increasingly count. Now the leading companies, 'the Pharmas', have the driving influence on lifestyle, well-being and health outcomes. Their interests and investments have a major impact on the nature and availability of drug treatments, and on the essence and conduct of medicine, worldwide.

The surge towards globalisation since the 1990s has placed the pharmaceutical industry where it is today. The Pharmas are now centred in the USA – which represents half the global market – and mainly reflect American health values and ways of doing things. The Pharmas are also

major instruments of US foreign policy, and their interests are well defended as such.

Pharmageddon stands for the lament that the state of world health represents a colossal waste of what medicine and medicines could accomplish, by structurally harnessing all the talent, energy and commitment that is there. Increasingly this is not happening, which is neither morally defensible, nor in the best interests of our future. It is damaging to the climate of health, the oxygen of community and the core of personal well-being.

Pharmageddon is marked by the contrast between over-medication and drug deprivation; it also implies a strong causal link between the two. Under-medication in poorer communities, and over-medication in richer ones, are connected as closely as obesity and malnutrition, like two sides of the same coin.

Intensive drug marketing and excessive drug consumption has produced an industry whose capacity to innovate and provide is compromised, and whose viability seems increasingly to depend on systematic exaggeration of drug benefits and suppression of evidence of risks and harm. In place of transparency, the industry has now largely taken into its own hands the role of providing information to the public and professionals, filling the air with messages about health priorities, expectations and needs. The net result is a drug supply system that starves national health and sustains global health deprivation.

Outside the major drug markets, populations suffer and die because drugs they need are completely unaffordable, because trade rules block access, and/or for lack of relevant innovation. Elsewhere, the obsession with drug treatment, health observance and disease awareness, is producing nothing like the desired effects. The USA exemplifies this trend: it is beset by diseases of affluence,

most obviously by obesity, with diabetes and related complications. But in spite, and no doubt also because, of all the treatment options, fewer than one in twenty citizens manages to maintain a normal weight, eat a nutritious diet, take adequate exercise and not smoke.

For all this, the notion of *Pharmageddon* may still seem almost inconceivable – as did the risk and threat of Climate Change, just a few years ago. It is natural to deny risks when the misery in prospect results from so much good intent and great talent, and from the enjoyment of huge benefits, valued freedoms and countless goods. And because medicines are especially precious goods, the idea of *Pharmageddon* offends personal and vested interests alike.

Parallels seem to exist between health and environmental catastrophe. The issues compare to the relationship between a car journey and Climate Change: they are inextricably linked, but not remotely connected in scale or relevance in the average driver's mind. Just as Climate Change seems inconceivable as a journey outcome, so most personal experience of medicines flatly contradicts the notion of *Pharmageddon*.

As clinical practitioners, or individual consumers with access to medicines, most people have seen, felt, witnessed and/or imagined their sometimes miraculous effects and results. But, to pursue the analogy, the risk of *Pharmageddon* is to do with the way in which *all* drug travel changes the climate of health, even when so many individual drug journeys seem vital or worthwhile.

Both because and in spite of all the benefits of good medicine, it seems crucial to consider whether, collectively, we are rapidly losing sight and sense of health. Increasingly it seems we are. At least we need to challenge the dominant fallacy that drugs more and more resemble

magic bullets and offer ever better solutions for the main trials of life.

At the same time, we need to accept that *Pharmageddon* is not simply the product of malevolence, but the natural outcome of something like a 'conspiracy of goodwill' – a universe driven by self interest, but dominated by a complex of corporate bodies all competing to survive. If *Pharmageddon* seems to beckon, it is in spite of what everyone wants, not because of it.

That also applies to the Pharmas. All might be well if their products matched promise and met genuine health needs. In fact, the Pharmas are panicked by this huge shortfall and become more predatory, gluttonous, devious and oppressive, to try to compensate for it. Health outcomes drift further and further away from mainstream thinking; excessive promotion, data suppression and falsification, secrecy, bribery, fraud and deep conflicts of interest are increasingly revealed.

The consequences go far beyond the drug disasters that make the headline news. *Pharmageddon* implies that we have now arrived at a tipping point where leading companies devote their main energies to marketing lifestyle products, rather than on finding ways of meeting real medical needs. The brave new world in prospect is one in which commercial imperatives trump health priorities, when Pharmas and followers systematically change our understanding and experience of what it means to be human, flattening the distinctions between cultures, degrading the clinical arsenal, and developing vast numbers of drugs, most not needed and all purporting to be best. The net result is not only therapeutic disappointment, but also crushing pressures that no public health system could ever survive.

Many people have concerns about many different flaws in the present system of pharmaceutical medicine, but what do they all add up to? Our starting point is simply that the word, *Pharmageddon*, may mean something important and deserves to exist, if only as a description of forest rather than trees.

The etymology seems to fit. *Pharmageddon* conveys the idea of a battle between health and ill-health, right and wrong and for better or worse. It also challenges the tendency to take for granted that progress in pharmaceutical medicine leads naturally to better health. *Armageddon* was "the great symbolic battlefield of the *Apocalypse*, scene of the final struggle between good and evil". *Apocalypse* (Ἀποκάλυψις – APOKALYPSIS) literally means the lifting of the veil, "a term applied to the disclosure to certain privileged persons of something hidden from the mass of humankind..." (Wikipedia, 2007).

The time has come to lift the veil: the broader significance of the risks must be explored and revealed. If *Pharmageddon* is part of any future reality, we all need to know.

Sources, references etc: see www.socialaudit.org.uk

Appendix Two Curriculum Vitae

Charles Medawar's professional background is in consumer protection. He worked with Consumers' Association (1966-71) and was later elected to its Council (1971-74). After a stint with Ralph Nader, working in Washington DC, he returned to the UK to set up Public Interest Research Centre (a Registered Charity) and Social Audit (its publishing arm), where he led a small team which attempted to develop and apply methodologies for social accounting, reporting on the ways in which major companies interpreted and discharged various social responsibilities. Since 1977, Medawar has specialised on medicines policy and drug safety issues (in both developing and industrialised economies) and on matters of corporate, governmental and professional accountability relating thereto. Most of his work has been funded by a prominent Quaker foundation, the Joseph Rowntree Charitable Trust.

More recently, Medawar has held several appointments with the World Health Organisation, including the WHO Conference of Experts on the Rational Use of Drugs (Nairobi, 1985) and Rapporteur of the Working Group of Experts on National Drug Policy (1988). He is now a member of the WHO Expert Advisory Panel on Drug Policies and Management. He was a member of the Expert Advisory Panel on Consumer Interests and Health Education of the US Pharmacopeial Convention (1995-2000); Editorial Board of *Drug & Therapeutics Bulletin*, (1990-95); Chair, Investment Sub-committee, Committee of Reference of the Friends Provident Stewardship Trusts; Trustee, Allen Lane Foundation (1989-2001); Hon. Fellow, Centre for Environmental Accounting, University of Dundee; and Council member of SustainAbility Ltd.

During 2004/5, Medawar worked as a specialist advisor on the Parliamentary Health Committee inquiry into 'The Influence of the Pharmaceutical Industry'. He has also worked as a consultant to the Australian Department of Health and Aged Care (2000), and as external assessor for the Open University's MBA course in Life Sciences. During the 1980s, Medawar worked as scientific coordinator on a number of legally-aided class actions, and was responsible for generic research notably on actions relating to transmission of HIV to haemophiliacs via Factor VIII and other blood products; benoxaprofen (Opren/Oraflex); Toxic Shock Syndrome and dependence on benzodiazepine tranquillisers.

Medawar writes, broadcasts and lectures regularly on corporate social responsibility and medicines policy and safety issues. His most recent work (with Professor Anita Hardon) is *Medicines out of Control? Antidepressants and*

the Conspiracy of Goodwill (Amsterdam: Aksant Academic Publishers, 2004).
A publications list is available on request, but much of his recent work (1998-2008) can be accessed on the Social Audit website (www.socialaudit.org.uk) which now attracts over 1,000,000 visitors a year.