



# **Trusting Brands in Society**

## **The Quality and Value of Modern Medicine**

**Dr. Tim Evans**  
**Dr. Sean Gabb**  
**Alberto Mingardi**  
**Stephen Pollard**

### **Centre for the New Europe**

CNE is Europe's leading, Brussels based, free market think tank. An independent not-for-profit organisation, CNE attracts a high quality media success in Europe every day. Its events are some of the most popular and well attended in Brussels. And it has more than 10,000 downloads of publications from its main web site - [www.CNE.org](http://www.CNE.org) - every month. For more information on CNE work on healthcare visit its specialist web site: [www.CNEhealth.org](http://www.CNEhealth.org).

## The Authors

**Dr. Tim Evans** is the president and director general of the Centre for the New Europe (CNE) Europe's leading, Brussels based, free market think tank. A former executive director of public affairs at the Independent Healthcare Association in London, he has also been an assistant director of the Foundation for Defence Studies and a senior policy consultant at the Adam Smith Institute. In 1991 he was the chief economic and political adviser to the Slovak prime minister in the former Czechoslovakia and was head of the prime minister's policy unit. In that year, he was the highest-ranking political adviser in the former Soviet bloc.

The author of numerous books, monographs and articles, he has been published by the Adam Smith Institute, the Fabian Society, the Institute of Economic Affairs, the Fraser Institute, the Libertarian Alliance, the Heritage Foundation and the Independent Healthcare Association. A regular commentator on television and radio, his articles have appeared in *The Guardian*, *The Economist*, *Financial Times* and *Wall Street Journal Europe*. In 1993 he was awarded his PhD from the London School of Economics. Today, he lives in Brussels with his wife Helen – and two cats Basil and Freddie.

**Dr Sean Gabb's** career has spanned the worlds of business, government service, academia, journalism, the media, politics and public affairs. A former political and economic adviser to the Slovak Prime Minister, he is also an experienced broadcaster on both radio and television, and has appeared on programmes in Britain, the USA, Canada, Argentina, Sudan and various world-wide networks. He has notched up over 250 appearances on major news programmes, documentaries, debate programmes and chat shows, including *Newsnight*, *The Midnight Hour*, *Scottish Question Time*, and *The World Tonight*. He is consulted as an expert on civil liberties issues, economic freedom and the open society. A prolific writer, his essays and monographs have been published by a wide range of institutions, including the Social Affairs Unit, the Independent Healthcare Association, the Adam Smith Institute, and the Libertarian Alliance, on such topics as constitutional law, health policy, religious freedom, civil liberties, history and economics and economic policy.

**Alberto Mingardi** is a Senior Fellow at the CNE and an Executive Director of the Italian award-winning free market think tank Istituto Bruno Leoni (IBL) - [www.brunoleoni.it](http://www.brunoleoni.it) - for which he covers issues related with globalization, competition and welfare reform. A prolific scholar and journalist, Mr. Mingardi is a columnist with a number of Italian newspapers - including "Il Riformista", "Libero", "Il Foglio", "L'Indipendente". His English-language writing has appeared in different publications, including the *Wall Street Journal*, *Markets and Morality*, *National Review*, *Religion and Liberty*. He lectures regularly in Italy and abroad.

**Stephen Pollard** is a senior fellow at the CNE and the director of its health forum. Mr. Pollard has a background in policymaking, having formerly been research director of the Fabian Society, the centre left think tank, and head of research at the Social Market Foundation. In those capacities, he has advised both the British Labour and Conservative parties. Once described on the front page of the *Sunday Times* as a 'Labour Guru', he recently conducted a seminar at 10 Downing Street on public service reforms.

He is a political columnist who writes regularly for many newspapers including *The Times*, *The Sunday Telegraph*, *The Independent*, and *Wall Street Journal Europe*. From 1998-2000 he was a columnist and chief leader writer on the *Daily Express*. He recently published a major biography of David Blunkett, the former British home secretary, and he is a senior fellow at Civitas, the Institute for the Study of Civil Society, in London. He is author of numerous pamphlets and books on health and education policy, and is co-author with Andrew Adonis of the best-selling *A Class Act – the Myth of Britain's Classless Society*.

## **Contents**

<b>Executive Summary</b>	<b>4</b>
<b>1. Introduction</b>	<b>6</b>
<b>2. Understanding the Complexities of the Research Based Industry</b>	<b>7</b>
<b>3. The Quality and Value of Modern Medicine</b>	<b>8</b>
<b>4. The Value and Integrity of Research-Based Medicines</b>	<b>10</b>
<b>5. The Environment of Decision-Making</b>	<b>12</b>
<b>6. The Case for Regulatory Oversight</b>	<b>13</b>
<b>7. Controlled Release of Information</b>	<b>16</b>
<b>8. Institutionalised Asymmetric Information</b>	<b>17</b>
<b>9. Let the Public Speak and Decide</b>	<b>18</b>
<b>10. A Balanced Way Forward</b>	<b>19</b>
<b>11. Conclusion: Trusting Brands, Listening to People and the Need for Better Education</b>	<b>21</b>

# **Trusting Brands: The Quality and Value of Modern Medicine in Society**

## **Executive Summary**

- The research-based pharmaceutical industry has achieved and is achieving what would once have been regarded as miracles. It has created new branded products that cure or alleviate sickness and that have extended both the length and quality of life.
- At every stage of their development, medicines are subject to a series of stringent tests and regulations to demonstrate their safety, efficacy and quality. Even after a medicine has been licensed, it remains subject to close scrutiny and post-marketing surveillance procedures to identify quickly any unforeseen side-effects.
- Yet today, consumers too often lack public trust and confidence in these products. Unduly alarmed by unscrupulous media hype and political scare mongering, society now faces the prospect of having personal and public healthcare unnecessarily undermined by an on-going series of moral panics and counter-productive scares.
- Today, there is a real and urgent need to rebuild trust between people and the medicines they use.
- At a time when - in reality - medicines are highly safe and hugely beneficial to personal and public healthcare, people are unnecessarily fearful.
- Fuelled by populist tales of pharmaceutical companies engaging in 'excessive profiteering', the production of 'dangerous products' and generally 'unethical behaviour', much criticism of the research-based pharmaceutical industry seems to proceed from a general and, in our view, inappropriate hostility to private business and a lack of understanding about the industry.
- Yet, given the demonstrable value and quality of today's medicines, the fact that consumers unnecessarily lack trust and confidence in them raises serious and profound challenges for us all - as well as potential dangers to people's own health.
- The authors of this paper believe that people should be encouraged to better understand the real benefits of the research-based industry and the medicines they produce. To give people a more truthful and objective understanding of the products available, their trust and confidence should be re-built via an active agenda of education and open communication.

- Today, government, industry, patient groups, journalists and medical professionals should rise to the challenge of trust and actively encourage better education:
  - On the processes of how innovative medicines are brought to market.
  - So that people can understand the regulations and the markers of quality already in place for medicines.
  - To actively engage medical professionals, patient groups, the public and pharmaceutical companies in a positive and more open dialogue appropriate for the twenty first century.
- Overall, the present regulatory framework is sound and ensures that new products are as safe as they can humanly be when introduced to the market. At every stage of the process, the burden of proof is solidly on the manufacturer to demonstrate that a product meets high standards of safety, quality and efficacy. If this cannot be shown beyond reasonable doubt, the medicine cannot be marketed to prescribers.
- Today, the level of regulation governing the development, testing, manufacture and supply of pharmaceutical products is already large and growing.
- Nevertheless, because we have an increasingly complex and dynamic pharmaceutical market, this regulatory framework should be adjusted so that it empowers pharmaceutical companies to speak directly with ordinary people, and so that ordinary people can tell the companies and each other about the medicines they want.
- However, this is not an argument for a completely unregulated market in pharmaceuticals and information. There is no public demand for that. Instead, what is suggested is that the present dialogue between medical professionals, patient groups, the general public, regulators and the pharmaceutical companies should be made less exclusive. It should cease to be a dialogue and widened into an informed discussion between the professionals and the companies – plus intermediaries trusted by the public and by ordinary people themselves. There may well be limits to what ordinary people can decide for themselves. Undoubtedly, though, ordinary people can be trusted to know, to exchange, and to decide more than is presently allowed.

# Trusting Brands: The Quality and Value of Modern Medicine in Society

## 1. Introduction

There is a question in the present debate on the pharmaceutical industry that many ask, but few are attempting to answer. This is what do people really want from a medication? A subsidiary question to this would be what ought to be the role of ordinary people in finding the answers?

There is no doubt that the research-based pharmaceutical industry in the United Kingdom and around the world has achieved and is achieving what would once have been regarded as miracles. It has created innovative new products that cure or alleviate sickness and that has extended both the length and quality of human life. Delivering highly cost effective solutions to people and governments, they have helped countless individuals improve their quality of life and helped health purchasers to improve the wider public health. This much they have achieved so far. There is every reason to believe that the future will bring still greater progress.

Yet for all of this, consumers today all too often lack public trust and confidence in these vital products. Often unduly alarmed by unscrupulous media hype and political scare mongering, society now faces the prospect of having personal and public healthcare being unnecessarily undermined by a series of supposed moral panics and highly counter-productive scare stories.

Today, consumers often sadly lack the trust and confidence that they should have in these products. At a time when - in reality - medicines are highly safe and hugely beneficial to personal and public healthcare, people are unnecessarily fearful and concerned.

It is in this context that this paper argues that public sentiment should be put onto firmer and more objective terrain.

As the Task Force on Medicines Partnership eloquently argues<sup>1</sup>: "...the differences between the patient's beliefs and understanding of the diagnosis and proposed treatment, and those of the health professional are crucially important. The health professional has a set of beliefs ... shaped by the content of professional training, and on the evidence from a large body of scientific research. The patient has a different, but equally cogent and coherent set of ideas about their own illness, medicines in general and their medicines in particular. These are based on their own preferences, priorities, beliefs, attitudes and life experience".

In short, people's trust in the quality and value of modern medicine must be actively rebuilt. This trust is not simply important to the industry that produces the innovative solutions in medicine. More importantly, it is vital for the people and patients who

---

<sup>1</sup> <http://www.medicines-partnership.org/index.asp?pgid=776> - visited on 14<sup>th</sup> March 2005

ultimately have the most to gain from their products. Better trust means better compliance, which means better outcomes and ultimately better public health.

## **2. Understanding the complexities of the research-based industry**

For all benefits they have brought to society, the pharmaceutical companies have never been popular in the way that companies like Compaq and Apple Mackintosh have become. Often misunderstood and distrusted, their successes are all too easily lost in a world dominated by headline grabbing politicians and journalists ready to promote the next moral panic.

For example, since September 2004, the Health Select Committee of the House of Commons has been examining the influence in Britain of the pharmaceutical industry. Led by Labour left winger, David Hinchliffe MP, the Committee has looked at how the industry affects government, regulators, healthcare professionals and consumers, and at the effects of this influence on public health.

Fuelled by populist tales of pharmaceutical companies engaging in 'excessive profiteering', the production of 'dangerous products' and generally 'unethical behaviour' the Committee examined witnesses and considered written submissions by interested persons and organisations.

While charges are often made against the industry, the public record shows that most are not justly laid, much criticism of the pharmaceutical industry seems to proceed from a general hostility to private business and a widespread lack of understanding about this industry in particular. A widespread assumption is that profit is at least an indecent companion to the search for cures and palliatives for human illness. But what other model is there for the development of pharmaceutical products that work? The Soviet and Chinese state pharmaceutical industries never amounted to much in terms of research and development of products that were useful to ordinary people or even useful for their stated purpose. The private companies in the free world at least do create new and useful products. And all this research and development costs money.

Taking into account research and development and regulatory compliance, it costs about US\$800 million to bring a new medicine to market.<sup>2</sup> Many of these costs are incurred whether or not the medicine actually reaches the market.

For every one new innovative product put on the market, 5,000 chemical formulations do not make it: either they fail safety tests, they do not work as expected or they are outperformed or simply beaten to market by a rival product. Once on the market, they have only a few years of profitability before the patent protection expires, or before an improved product is released by another company. A recent study of 100 pharmaceutical products showed that the profits earned on most of them did not cover investment costs.<sup>3</sup>

---

<sup>2</sup> Dennis Owens, "Net pharmacies are on thin ground", *The National Post*, Ottawa, 3<sup>rd</sup> March 2004.

<sup>3</sup> *Ibid.*

Therefore, it is entirely reasonable that the pharmaceutical companies should try to make a profit on those products that do come to market.

### 3. The Quality and Value of Modern Medicine

Here, it is worth mentioning in some detail the path by which new pharmaceutical products actually come to market. The protection of public health remains the overriding objective throughout the approval process for a new medicine. If evidence of previously unknown or uncommon yet important adverse drug reactions or of quality problems comes to light, following a medicine's approval, this is not because of any systemic failure of the pharmaceutical companies or the regulatory process. Knowledge is never perfect and medicine is not an exact science. Even so, the path by which new products come to market is as nearly perfect as any set of human arrangements can be made.

The first attempt at regulating the pharmaceutical sector in the United Kingdom was made in The Apothecary Wares, Drugs and Stuffs Act 1540. This was followed most significantly by the establishment, in 1864, of the British Pharmacopoeia, a compendium of monographs providing officially-recognised quality standards for many drugs and drug products still in use today. In Europe, in the early 1960s, thalidomide, a drug which was meant to ease morning sickness in pregnant women, was found to have a terrible side-effect: women who used the drug gave birth to babies with severe defects. This led to the Medicines Act 1968, which has been the basis for the control of pharmaceuticals since then.

The main object of the present regulatory framework is to ensure that newly-licensed medicines meet high standards of safety, quality and efficacy when introduced to the market. At every stage of the licensing application process, the burden of proof is solidly on the manufacturer to demonstrate that its product and the conditions in which it is to be manufactured, marketed, distributed, sold and supplied are of the highest quality. If it cannot meet these standards, the medicine cannot be introduced. The stages of establishing the safety, quality and efficacy of a new product are as follows:

**First**, a product must be examined for toxicity – is it dangerous to any significant degree? What is meant by significant toxicity depends on the intended use of the product. For cancer, for example, many products do cause unwanted, sometimes serious side-effects, but are judged acceptable where they can be shown to cure or alleviate potentially fatal illnesses. This closely-regulated testing must be completed before 'clinical trials' take place. This basic safety being established, the product can now be tested in carefully controlled doses on healthy human volunteers.

**Second**, its basic safety established, a product now proceeds to a further round of clinical trials, where it is tested on a small number of patients suffering from whatever illness it is intended to treat. The purpose of this stage is to provide evidence of effectiveness and to establish the range of effective dosage.

**Third**, this done, the product is given to a large group of patients and its effectiveness compared to a placebo (a dosage form which appears identical, but

has no active ingredient) and, often, to an already licensed, comparable drug which treats the same condition. Often “double blind” trials are conducted - whereby even the doctor does not know whether they are administering the new drug, a placebo or comparator - in order to eliminate the possibility of any bias in the results or evaluation. The whole process of a clinical trial is strictly regulated (indeed, a new EU directive governing the conduct of clinical trials was adopted in December 2000).

**Fourth**, while the product is being tested, its precise formulation and manufacturing process will be developed. Stability studies will be conducted with the final formulation to establish the product's shelf life.

**Finally**, when all this has been done, the evidence thereby collected will be submitted to the relevant regulatory authority and a licence application will be made. A licence will be granted only when the regulator is satisfied that all necessary tests have been completed as they ought to be and that the product is proven safe beyond reasonable doubt, is efficacious and of high quality. It is therefore not surprising that for every product given a licence, many hundreds will have failed – they will have failed one of the early stages of testing, or the regulator is unconvinced that the product will be safe or effective.

Even now, however, the process of testing is not ended. Once a licence to market a medicine has been granted, there are systems in place for reporting side-effects and other adverse effects. These systems are designed to ensure continued data collection and identify issues undetected by previous clinical trials: this process is called pharmacovigilance. If serious problems are detected, immediate action is taken either to alert the medical profession to the risk, in some instances, to change the labelling or, in extreme cases, to withdraw the product from the market. British law requires product licences to be renewed every five years, at which stage all additional data is reviewed by the regulatory authority.

Then there is the manufacturing process. Products must be manufactured so that they are consistent within and across batches, and so that there is no risk of contamination. Before the Medicines and Healthcare Products Regulatory Agency (MHRA) will grant a manufacturing licence, a product must be shown in its manufacture to comply with Good Manufacturing Process. These are laid down by statute. They used to be a matter for the British Government to set alone. Since a Directive made in 1991, these are now handled by the European Union.<sup>4</sup>

Therefore, the level of regulation governing the development, testing, manufacture and supply of pharmaceutical products is already large and growing. This is very expensive for the pharmaceutical manufacturers. Since 1980s, there has been a 25-fold increase in research and development costs. During this time, the cost of bringing a new medicine to market has risen dramatically, and the time taken to develop and test the product has risen to 10 years.<sup>5</sup>

Compare all this with the process by which other products come to market. Computers, cars, household devices, and so forth, all involve considerable potential

---

<sup>4</sup> The above section relies heavily on Peter Gough, *Regulation of the pharmaceutical industry*, published by the Institute of Quality Assurance, London, 2005.

<sup>5</sup> Luke Johnson, “Hey, big pharma – what’s going on?”, *The Sunday Telegraph*, London, 20<sup>th</sup> February 2005.

harms – to their users and to others. We need say nothing about the dangers of the motor car or about the endless product recalls over the past generation that have shown defects in design and manufacture processes.

According to some, the heavy use of computer equipment can lead to repetitive strain injuries or even perhaps to cancers; particularly now that computers increasingly involve some kind of local radio transmission. Even so, these products are either lightly regulated in their design and manufacture or not regulated at all. If there have been problems with new pharmaceutical products, the cause is not at all that profit-hungry manufacturers have hurried untested or dangerous products to market. The reason, as said, is that medicine is not an exact science and there will always be instances where previously unknown side effects or uncommon but significant adverse incidents only come to light after a medicine has been on the market for some time. As Professor Nicholas Moore of INSERM argued eloquently in a recent edition of the BMJ<sup>6</sup>, “Real risks need to be discovered and assessed in real use. Patients and prescribers’ imagination and risk in drug use and misuse is infinite. Post-marketing drug risk assessment relies on multiple simultaneous methods.”

In spite of all this care and regulation, the British pharmaceutical industry has been conspicuously successful. It employs in this country some 65,000 of which about 20,000 work in R&D (ABPI). It creates exports worth £12 billion. The two largest British producers supply almost 11 per cent of the total world market. More than half the major products sold in the world were developed in the United Kingdom.<sup>7</sup> And, with the cost of the NHS rising, the medicines bill consistently remains at about 13 per cent of the total, despite a constant growth every year in the number of prescriptions issued.<sup>8</sup>

#### **4. The Value and Integrity of Research-based Medicines**

Yet today, the research-based pharmaceutical industry is under attack as never before despite the significant and quantifiable contribution it has made to improving public health through important innovative discoveries:

- Statins for example, the ground-breaking medicines widely used for people with heart conditions, now save more than 6,000 lives each year in the United Kingdom. Crucially, 1.8 million people there enjoy a measurably better quality of life with these innovative products than would otherwise have been the case.
- The development of ACE inhibitors in the 1980s has a major beneficial effect on patients with heart failure.
- The discovery of the polio vaccine heralded the end of a disease which affected the spinal cord and the brain and often resulted in paralysis, wasting of the limbs and sometimes death.

---

<sup>6</sup> British Medical Journal, 5<sup>th</sup> March 2005

<sup>7</sup> Ibid.

<sup>8</sup> <http://www.abpi.org.uk/statistics/section.asp?sect=4#20> visited on 14<sup>th</sup> March 2005

- The development of oral contraceptives gave women control over their fertility and their lives. Early versions were followed by lower dose pills with reduced side-effects.
- Genetic engineering produced the first therapy for human use with production of genetically engineered insulin in 1982. About 80 per cent of diabetics now use this type of insulin.
- New short-acting anesthetics have enabled an increase in day-case surgery, thus allowing patients to go home on the same day as their surgery.
- The development of inhaled steroids has had a profound effect on the treatment of asthma.
- The treatment of peptic ulcers was revolutionized in the 1970s by the discovery of H<sub>2</sub>-blockers which reduce the amount of acid produced in the stomach. Long spells in hospital and deaths from ruptured peptic ulcers are now rare.
- Advances in medicines have reduced hospital in-patient time of 12 major diseases, including mental illness and infectious diseases, saving the NHS £10 billion per year, twice the cost of all NHS medicines.

All these innovations and other life-saving and life-enhancing treatments, were developed after many years of investment by the research-based pharmaceutical industry.

However, a disparate array of anti-capitalists and litigation lawyers has seemingly identified the industry as easy targets with deep pockets. Endlessly attacking what they insist are excessive profits, overpriced prescription drugs, and flawed clinical trials they choose to promote the prospect of a Utopian risk-free life and a world without commercial incentive.

The key to continued pharmaceutical innovation is ongoing investment in research and development. The research-based industry continues to invent important new classes of medicines that dramatically advance the treatment of diseases and conditions in areas of unmet clinical need such as, HIV/AIDS, Parkinson's disease, Alzheimer's disease, schizophrenia and diabetes. Patients who just a few years ago faced decline and disability now have new treatment options that help them live healthier, more productive lives.

The public value inherent in medicines is brought clearly into focus when one compares daily spending on medicines with the other common ways in which we spend our money. In 2003, UK consumers spent 58p per day on television, 67p per day on restaurant meals and £1.33 per day on clothes and shoes. Education cost the public purse £2.52 per day and defence £1.12 per day. Medicines cost just 40p per day.<sup>9</sup>

---

<sup>9</sup> Daily Expenditure 2003 available online at <http://www.abpi.org.uk/statistics/section.asap?sect=4> (visited 14<sup>th</sup> March 2005)

Advances in new medicines have come even as the length, complexity, risk, and costs involved in the R&D process continue to grow. New innovative discoveries are enabling a better understanding of the nature of many diseases and conditions. Potential treatments for more complex diseases require more time to study, more investment and they are often more difficult to evaluate.

The research-based pharmaceutical industry invests over 30 per cent of its annual sales in R&D, compared to equivalent figures of 11 per cent for the aerospace industry and 3½ per cent for the automobile industry.

Moreover, the producers of the innovative branded medicines are working to continually improve the manufacturing, packaging and supply chain processes. The aim is to protect the integrity of the medicines that patients receive and both justify and enhance public confidence and trust in medicines.

A key area for investment is in packaging and labelling. Recent developments in tracking and traceability technology range from basic bar coding standards to radio frequency identification technology (RFID)<sup>11</sup> These enable individual packs of medicines to be uniquely identified and verified as authentic product by the manufacturer, assuring pharmacist and patient that the medicine in question is genuine and fit for purpose. In a similar vein, the industry is investigating tamper-proof packaging and colour-shifting ink labels, and upgrading manufacturing facilities to adopt these latest technologies to assure the quality of medicines from the factory floor to the patient's home.

## **5. The Environment of Decision Making**

Yet for all their successes, the pharmaceutical industry is still seen by too many as greedy, secretive and indifferent to the wishes or even needs of patients.

The Consumers' Association, for example, believes that ever more and better regulation is needed. In its own submission of August 2004 to the Commons Health Select Committee, it argued "The Medicines and Healthcare products Regulatory Agency (MHRA) needs to ensure that all its work is undertaken in the interests of public health protection."<sup>12</sup> It further argues:

Responsibility for monitoring all forms of pharmaceutical industry advertising and other promotion should be transferred to a new, independent advertising and information regulator. This regulator should adopt and proactively implement robust and transparent procedures to prevent misleading promotional campaigns - including all forms of covert promotion - as far as possible at the outset, and to take swift and effective action when these do occur.<sup>13</sup>

---

<sup>11</sup> Clive Cookson, 'Procedure to tackle drugs fraud passes test', *Financial Times*, 14<sup>th</sup> March 2005

<sup>12</sup> Health Select Committee Inquiry into The Influence of the Pharmaceutical Industry: health policy, research, prescribing practice and patient use – August 2004 Memorandum from Consumers' Association, para. 1.5 - published on line at: [http://www.which.net/campaigns/health/medicines/0408pharma\\_scomm.pdf](http://www.which.net/campaigns/health/medicines/0408pharma_scomm.pdf) (checked February 2005)

<sup>13</sup> *Ibid.*

What reason, however, is there to suppose that more regulation is really needed? Undoubtedly, we live in an age where regulation is seen as the solution to every problem. As in the rest of the English-speaking world, Britain is subject to a heavy and growing weight of regulation. This is not the place to discuss whether any specific regulation is justified. It is enough to say that there is a general assumption among those who matter that everything that is done by the people must be known to the authorities and controlled by them.

During the ten years to the 21<sup>st</sup> February 2005, the phrase “completely unregulated” occurs 153 times in the British newspaper press. In all cases, unless used satirically, the phrase is part of a condemnation of some activity. We are told that the advertising of food to children,<sup>14</sup> residential lettings agents,<sup>15</sup> funeral directors,<sup>16</sup> rock climbing,<sup>17</sup> alleged communication with the dead,<sup>18</sup> salons and tanning shops,<sup>19</sup> contracts for extended warranties on home appliances,<sup>20</sup> and anything to do with the Internet - that these are all “almost completely unregulated” or just “completely unregulated”, and that the authorities had better do something about the fact.

## 6. The Case for Regulatory Oversight

Yet, the assumption behind much of what was presented to or discussed in the Select Committee hearings appears to have been that whatever wrong or merely questionable might have been done by pharmaceutical companies could have been avoided by a better scheme of regulation, and that, any problems uncovered, the best use of intellectual effort must now be in devising a better scheme for the future. But this begs the question what went wrong with the regulations already in place?

The answer is that the present regulatory body for the pharmaceutical industry - the Medicines and Healthcare Products Regulatory Agency (MHRA) – seems for some people to have been too close to the industry for effective regulation to have taken place. However, what appears to have happened with pharmaceutical regulation is not some aberration that can be improved with a new legal framework. It is no more than the illustration of a general tendency.

The justification for a regulatory body where pharmaceutical products are concerned is what economists call “market failure”. The mainstream defence of the free market rests on the claim that it allocates resources more efficiently than any other system. To speak formally, it tends to bring about both productive and allocative efficiency. This first means that goods and services are produced at the lowest currently known cost. The second means that production satisfies the known wants of consumers in the fullest way currently possible.

---

<sup>14</sup> Maxine Frith, “With one in four children overweight, the experts explain what can be done about it”, *The Independent*, London, 26<sup>th</sup> May 2004.

<sup>15</sup> Miles Bagnall, “Just don’t let them get away with it”, *The Guardian*, Manchester and London, 15<sup>th</sup> May 2004.

<sup>16</sup> Cara Page, “Shocking cost of dying”, *The Daily Record*, Glasgow, 11<sup>th</sup> May 2004.

<sup>17</sup> Ian Parri, “Feedback”, *The Daily Post*, Liverpool, 31<sup>st</sup> December 2003.

<sup>18</sup> Nick Curtis, “and if you want to find a psychic”, *The Evening Standard*, London, 12<sup>th</sup> September 2003.

<sup>19</sup> “Will You Sleep Well After Sessions On Sunbeds?”, *The Batch Chronicle*, Bristol, 14<sup>th</sup> April 2003.

<sup>20</sup> Teresa Hunter, “Travel agents and electrical retailers ordered to play fair”, *The Sunday Herald*, Edinburgh, 27<sup>th</sup> October 2002.

We can best see this argument in the analysis of firms under perfect competition. Let it be granted that there are many buyers and sellers in a market; that all the goods produced in this market are of the same quality; that there are no barriers to entry or exit for any player in the market; that there is perfect knowledge among all players in the market regarding prices and production methods. Given these assumptions, an equilibrium between demand and supply will come about that maximises social welfare. Any intervention by the authorities in such a state of affairs will produce a loss of welfare.

Now, such an equilibrium never comes about in the real world. It certainly never comes about in the pharmaceutical product market. There are not large numbers of buyers and sellers, nor are any two pharmaceutical products the same – instead, there is a group of very large companies with virtual monopolies in certain products, facing a virtually monopsonistic buyer in each national market: in Britain, this is the National Health Service. There are obvious barriers to entry and exit. Above all, there is not perfect knowledge. There is instead what is called the problem of asymmetric information.

The pharmaceutical companies know all that can be humanly known about their products: the consuming public knows almost nothing, and is not thought able to learn what needs to be known. This being so, the overwhelming consensus of opinion is that some regulatory body is needed to stand between the pharmaceutical companies and the consuming public. The functions of this body are to ask the appropriate questions, and only to allow products to be sold if the answers are satisfactory. Given sufficient zeal by or trust in the regulatory body, there is no need for the public to ask its own questions. Indeed, there is a case for the public not to be allowed to find out information for itself. The public may be too ill-informed about the nature of what is being discussed to understand the nature and quality of the information provided – especially as much information will come from sources that are themselves ill-informed. Therefore, in the United Kingdom, the Medicines and Healthcare Products Regulatory Agency also bans the advertising of pharmaceutical products, and a very tight control over what information can be released to the public.

The main problem with this approach, however, is not incidental but systemic. It is what public choice economists call “regulatory capture”. The phrase comes from Gabriel Kolko, a Marxist historian, who reworked his doctoral thesis into the *The Triumph of Conservatism: A Reinterpretation of American History, 1900-1916*, published in 1963<sup>21</sup> and followed it up with a more detailed study of a single industry in *Railroads and Regulation* in 1965.<sup>22</sup>

The basic mechanics of regulatory capture are straightforward. People give more attention to a particular law or agency if they feel that they have something at stake. They will make sure to know about laws and policies that affect their own interests. If those people are running a wealthy business, they will have a lot at stake, and will correspondingly make sure to be fully informed.

---

<sup>21</sup> Gabriel Kolko, *The Triumph of Conservatism: A Reinterpretation of American History, 1900-1916*, The Free Press, New York, 1963 – selections available on line at: <http://users.crocker.com/~acacia/kolko.html> (checked February 2005)

<sup>22</sup> Gabriel Kolko, *Railroads and Regulation, 1877-1916*, Princeton University Press, Princeton, N.J. 1965

Now, regulators may at first feel hostile to their subjects. Over time, however, regulators and the regulated get to know each other and to work together, with or without any real sense of cooperation. The regulated, who provide information and make a show of cooperation, earn the appreciation of regulators, who find that endless crusade takes its toll in energy, enthusiasm, and efficiency. Regulators find that if they cooperate with their subjects in some areas, they will get cooperation back on others.

There is no need for regulators and regulated to like each other. Often they do not. They still work together. Regulators hardly ever want to destroy what they regulate. Most often, they see their job as simply a matter of imposing the public interest on otherwise irresponsible organisations. And the regulated usually regard the regulators as facts of life to deal with, and better cooperated with than resisted.

Regulated firms end up supplying not just data to regulators, but personnel. After all, who understands the field better than folks who are retiring or resigning from the field's major participants? Few people want regulations made in outright ignorance. The result is a regulatory agency staffed by former or perhaps future colleagues of those in the regulated firms.

Regulation, then, may not be the only solution. Anyone who expects new pharmaceutical products to be completely effective and completely safe and the pharmaceutical companies to love their customers more than their balance sheets, is asking for a perfection that cannot – and in some senses should not - be on offer. For in all of this, we are talking about human beings and the resources to further innovate and solutioneer.

Nevertheless, we can hope to improve on the existing situation. The central questions are of information and trust. How can it be generally known which pharmaceutical products work for patients? And how can we trust claims about what does work? Part of the answer at least lies in diversity of information.

As said, we live in a world of centralised information about pharmaceutical products. Ordinary people are not expected or fully allowed to learn for themselves about the value of any particular medication. Therefore, information about any specific product is of two kinds. First, there are the impenetrable and often secretive conversations that take place between the pharmaceutical companies and the regulators of the medical profession or both. Second, there are the completely unregulated and frequently unlikely claims that circulate on the Internet – some websites, for example, recommend Prozac as an appetite suppressant.<sup>23</sup> Between these extremes, there is at best limited room made for informed debate about pharmaceutical products.

---

<sup>23</sup> See, for example, <http://helpuniversity.com/pharmacy/weight-loss/phentermine-prozac-for-weight-.html> (Checked September 2004).

## 7. Controlled Release of Information

Much has happened since the high age of confidence in government. But what Douglas Jay – a Minister in the Labour Government of the day – once said, still largely holds for many:

[I]n the case of nutrition and health, just as in the case of education, the gentleman in Whitehall really does know better what is good for the people than the people know themselves.<sup>24</sup>

Today, we have an increasingly complex and dynamic pharmaceutical market in which it has been reasonable to see untrained members of the public as incompetent to make informed choices about products, and we have a medical profession and set of regulatory agencies expected and empowered by law to make their choices for the public.

That is why there are presently advertising controls in many European countries. These are now codified in the commercial law common throughout the European Union. Directive 2001/83/EC on the Community code relates to medicinal products for human use. This Directive prohibits the advertising of prescription only medicines to the general public. Indeed, it goes further in suggesting that rules are needed for all pharmaceutical products, whether or not prescribed:

Advertising to the general public, even of non-prescription medicinal products, could affect public health, were it to be excessive and ill-considered. Advertising of medicinal products to the general public, where it is permitted, ought therefore to satisfy certain essential criteria, which ought to be defined.<sup>25</sup>

Even before this blanket prohibition came into force within the European Union, many national jurisdictions had adopted into their product liability laws some variant of the American “learned intermediary rule”, whereby pharmaceutical suppliers were under a duty to warn only the physician intermediary, not the patient. Such rules essentially immunised the pharmaceutical manufacturer in most failure-to-warn cases. Injured, uninformed patients were expected to proceed against the doctor for negligence, typically for lack of informed consent.<sup>26</sup>

---

<sup>24</sup> Douglas Jay, *The Socialist Case*, London, Victor Gollancz, 1947, p. 258. Worth stressing here is that this was not some casual remark pounced on by a journalist and quoted out of context. It comes from the second revised edition of a book first published ten years previously, and is therefore the product of some consideration.

<sup>25</sup> The Directive is to be found at [http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l\\_311/l\\_31120011128en00670128.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_311/l_31120011128en00670128.pdf). (Checked February 2005). The quoted words are from para. 45 of the Preamble. See also Title VIII, on Advertising, and this from the preamble: “(44) Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities ( 2 ) prohibits the television advertising of medicinal products which are available only on medical prescription in the Member State within whose jurisdiction the television broadcaster is located. This principle should be made of general application by extending it to other media.

<sup>26</sup> For a full discussion of the American rule, see David J. Cooner, *The Intersection of Madison Avenue and the Learned Intermediary Doctrine*, [http://library.lp.findlaw.com/articles/file/00395/008727/title/Subject/topic/Products%20Liability\\_Learned%20Intermediary%20Doctrine/filename/productsliability\\_1\\_904](http://library.lp.findlaw.com/articles/file/00395/008727/title/Subject/topic/Products%20Liability_Learned%20Intermediary%20Doctrine/filename/productsliability_1_904) (Checked February 2005). David J. Cooner is a partner in the Firm of McCarter & English, LLP, and a member of the Firm's Products Liability Group. His practice has focused on representing medical product manufacturers, pharmaceutical and chemical companies, and other

## 8. Institutionalised Asymmetric Information

The effect of these regulations is not to protect the public from charlatans: the Internet is already full of charlatans. Their effect is to prevent informed discussion of pharmaceutical issues of a kind that ordinary people can understand. Because the pharmaceutical companies are prohibited by law from communicating directly with the public, the public must trust either what information is transmitted via the medical profession, or the wild claims of Internet salesmen based in the British Virgin Islands. At the same time, the pharmaceutical companies cannot reach out directly; they cannot truly know what their customers want. A system of regulation devised to solve the problem of asymmetric information has set this asymmetry in legal concrete.

Look again at the Internet claims about Prozac as an appetite suppressant. Anyone who thinks it can help with dieting may be misinformed. Whatever the case, Eli Lilly, the manufacturer of the product, is not allowed to publish a word about the correct uses of Prozac.

Again, there are websites that denounce the products of the pharmaceutical companies and instead recommend products that may be useless or actually harmful. These products include psychic surgery, faith healing, laetrile, and much else.

In 2004, the *Journal of Medical Internet Research* published a survey of websites providing information on complementary and alternative medicine. The researchers found that:

We found that most CAM Web sites were potentially harmful either by displaying statements that could cause harm, or by omitting vital information. However, our data suggest that available technical quality criteria fail to identify potentially harmful information online.

We found that one quarter of CAM Web sites present information that may cause physical harm if acted upon. These sites encouraged consumers to avoid conventional therapy, presented information on products that may be directly toxic, or presented information on products that may cause interactions with conventional medications. This is potentially dangerous because consumers have easy access to CAM products online and act upon what they see on the Internet., often do so without the knowledge or advice of clinicians.

Almost all (97%) CAM Web sites omitted vital warnings, drug interactions, contraindications, or adverse reactions. This is concerning because many consumers perceive "natural" products as safe. Further, many herbs that may be safe when used alone interact with conventional medications.<sup>27</sup>

---

companies in product liability matters, as well as representing healthcare professionals and business entities in a wide range of litigated matters.

<sup>27</sup> Muhammad Walji, MS; Smitha Sagaram, MBBS, MS; Deepak Sagaram, MBBS; Funda Meric-Bernstam, MD; Craig Johnson, PhD; Nadeem Q Mirza2, MD; Elmer V Bernstam, MD, "Efficacy of Quality Criteria to Identify Potentially Harmful Information: A Cross-sectional Survey of Complementary and Alternative Medicine Web Sites", *Journal of Medical Internet Research* 2004;6(2):e21 - <http://www.jmir.org/2004/2/e21/> (Checked

The pharmaceutical companies are often prevented by law from replying in detail to these claims, and from offering their own opinion about the effectiveness and best use of their own products. Anyone can set up a website to claim that Viagra can cure lung cancer. Pfizer, which developed the product, is not allowed within the European Union to say on its own website how it should best be used. Nor is there legal room for any other organisation independent of Pfizer or the regulators to speak authoritatively to the public.

## **9. Let the Public Speak and Decide**

We need a regulatory framework within which the pharmaceutical companies can speak directly with ordinary people, and in which ordinary people can tell the companies and each other about the medicines they want, and about what they hope from the medicines that are available. This inevitably means at least some relaxation in the controls of direct advertising of pharmaceutical products. There are many arguments in favour of such a liberalisation, but these are not here the point. The purpose of liberalisation here is to enable the growth of a conversation between producers and consumers.

It may be said that people really are not able to know what they want, or to understand the nature of what is offered to them. Whether this is a patronising assumption of superiority is beside the point. What does matter is that it is probably a false belief. Ordinary people may not be able to understand all the scientific details of a new pharmaceutical product, but they are surely able to decide whether it is potentially appropriate for them, and whether it is being offered in the way that they want. It is wrong to assume that an informed decision must rest on full information. Every consumer market in the world is filled with informed consumers who have nothing approaching full information. Hardly anyone in the world knows how a refrigerator works. They still somehow work out what capacity, size and shape and colour of refrigerator they want in their kitchens.

Even fewer people know how a mobile telephone works. And yet the average child of ten can explain what he wants from a mobile telephone, and which brand and network come closest to giving that. And these are in markets where no controls exist on what information may be given or exchanged.

Informed decisions do not require full information. They require information relevant to the decision. What is relevant depends on what is wanted from a product and on the capacity of individual consumers. These are facts that cannot be known to any outside agency, and cannot be known in advance. We can be sure, however, that, where matters of health or even life itself are concerned, consumers will on the whole make very informed decisions. Anyone who looks at the range of magazines available on consumer electronic products, on the detailed answers within them to questions put by the readers, and on the serious attention these magazines receive from people of apparently limited education, can imagine what would happen were

---

September 2004). See also Morag Mckinnon, "a dose of good advice works best", *Evening News*, Edinburgh, 31<sup>st</sup> March 2003.

the pharmaceutical market opened to the same public scrutiny and dialogue as any other market.

## 10. A Balanced Way Forward

If, then, we wish to further address the current public concern about the quality of the medicines provided by the pharmaceutical industry, we must look beyond a model of centralised regulation that, whatever its merits in the middle decades of the 20<sup>th</sup> century, is now outmoded. We must open the floor to discussion. This means letting the pharmaceutical companies speak directly to their final customers – more importantly, though, it means letting these customers consult among themselves and then tell the pharmaceutical companies what they really want.

How is this to be done? The short answer is that consumers need intermediary bodies between themselves and the pharmaceutical companies that they feel able to trust. These are companies so demonised by bad publicity that their word will not be taken automatically for granted. There is therefore a need for other bodies that will be trusted.

One such initiative is the Ask About Medicines Week campaign. This describes itself as:

an independent campaign to increase people's involvement in decisions about their medicines use. It came about through the unique coalition of the Task Force on Medicines Partnership, the Promoting Excellence in Consumer Medicines Information Working Group and the charity Developing Patient Partnerships.<sup>28</sup>

It has three key messages:

- everyone is entitled to be involved in deciding whether a medicine is right for them
- everyone should be able to get good information to make decisions about medicines, from the source they choose
- health care professionals need to help people make choices, and we support them in that<sup>29</sup>

This campaign and others like it are about empowerment. They seek to remove decisions about medication from the exclusive preserve of medical professionals – whose objectives and criteria may differ from that of their patients – and to involve ordinary people into the decision process.

But, as said, intermediary bodies are not the only means by which ordinary people are trying to share in or take control over the process of medication.

In a survey conducted in 2001 for the journal *General Practitioner*, nearly nine out of ten physicians thought patients were better informed than they were ten years ago,

---

<sup>28</sup> The Ask About Medicines website is at: <http://www.askaboutmedicines.org/>

<sup>29</sup> Ibid.

and 72 per cent said the Internet had increased the number of patients who self-diagnosed or demanded specific treatments.<sup>30</sup>

The medical world, then, has seen a cultural revolution in the past few years. Patterns of deference and acceptance of monopolistic access to information that was almost ingrained as recently as 1990 have been eroded. We are visibly returning to the more diverse medical environment of the past. Increasingly, people who visit physicians are less to be regarded as patients than as health consumers. They want from their physicians the same levels of service and interactive consultation as they take for granted from hairdressers and from travel agents.

Today, it must be accepted that ordinary people have the right to take part in decisions affecting their medication, and that there will soon be a vibrant market in reliable information.

Look at the car market. To repeat, most people have no understanding of how an internal combustion engine works. Even so, most people do know which car is best for their own needs. There has for generations been a free exchange of information about which car is best for which purpose. There are magazines in which the latest developments are explained and discussed. There are popular television programmes in which charismatic presenters frankly review the latest offering from the car manufacturers. There are guides in which are published the new and second hand prices of every car available on the British market. There is a vast body of personal experience which ordinary people willingly share with each other. Of course, there is also the internet. Undoubtedly, the car market is not wholly satisfactory, and there is some distrust of car manufacturers. But try to imagine how much worse this market would be had information within it been the exclusive preserve of the political class and their allies. Imagine how that market would be if consumers had to get a prescription from a qualified engineer before they could buy a car. The engineer might know more about the technical features of car engines than his “patients”. He might care deeply about their needs. But would there be the same wealth of diversity in this hypothetical market as there is in the real market? There would not. Instead, cars would be developed through an opaque dialogue between the qualified engineers and the car manufacturers. Cars would not do exactly what their buyers wanted. There would be a smaller variety of models. There would be less public confidence in the research and development process. And, given the economics of producer capture in markets from which ordinary wisdom was excluded, it is questionable whether cars would really be very much safer than they presently are.

This is not an argument for a completely unregulated market in pharmaceuticals and information. After all, there is certainly no public demand for that. Ordinary people expect pharmaceutical products to be carefully examined before they come to market so that they can be ensured as safe as can be reasonably achieved. What is here suggested is that the present dialogue between medical professionals and the pharmaceutical companies should be made less exclusive. It should cease to be a dialogue and widened into an informed discussion between the professionals and the companies – plus intermediaries trusted by the public and by ordinary people themselves. There may well be limits to what ordinary people can decide for

---

<sup>30</sup> Simon Crompton, “Trust me, I’m a doctor”, *The Times*, London, 8<sup>th</sup> May 2001.

themselves. Undoubtedly, though, ordinary people can be trusted to know more and to exchange more and to decide more than is presently allowed.

## **11. Conclusion: Trusting Brands and Listening to People**

Away from the media hype and moral panics that too often surround the discussion of modern healthcare, it is clear that the fruits of the research-based pharmaceutical industry are in reality already of the highest possible quality, safety, efficacy and integrity.

Indeed, given the value and quality of today's medicines, the fact that consumers are often unnecessarily lacking trust and confidence in them, raises serious and profound challenges for us all - as well as potential dangers to people's own health.

Today there is a real need to rebuild trust.

As such, the authors of this paper believe that people should be encouraged to better understand the real benefits and value of modern innovative medicines.

To give people a more truthful and objective understanding of the products available, their trust and confidence should be re-built via an active agenda of education and debate.

Today, government, industry, patient groups, journalists and medical professionals should actively encourage better education:

- On the processes of how innovative medicines are discovered, developed and actually brought to market by the research-based industry;
- So that people can understand the regulations and the markers of quality already in place for medicines;
- To actively engage medical professionals and the research based industry in a positive and more open dialogue appropriate for the twenty first century.

These measures are of vital importance if trust and truth are going to prevail in British and European health systems.

Given the seriousness of this issue – and that fact that people's lives are potentially at stake - it is vital that policy makers in government and beyond now pick this challenge up.

Today, it is time for trust to be rebuilt between people, patients and the medicines available.