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Thank you for taking the time to read Pharma Futurology, and for keeping an open mind about how the pharmaceutical industry will integrate with the rest of the world a decade from now. This is a vision that we felt needed to be communicated. Although there are other reports looking at the future of the pharmaceutical industry, these have tended to focus on transforming business strategy or on the various information and communication technologies that will be endemic in the biopharmaceutical industry in the coming years. What they have missed is the bigger picture – the healthcare ecosystem; the connected world.

In our experience, poor connectivity is a rate-limiting step for further development. BT has spent years connecting people, businesses and technologies. We know about the importance of joined-up thinking, and how different elements in a system need to communicate with each other. Nevertheless, the process of developing Pharma Futurology was fresh and revelatory for many people within the company. It sparked excitement and illuminated new research projects and avenues to explore, to improve the services, products and overall business solutions we offer.

Pharma Futurology probes the areas of convergence within the entire healthcare network. Truly innovative convergence is about more than simply linking a number of similar elements; it is about creating ways to connect two totally separate entities that in union are greater than the sum of their parts. This idea is best summed up in the words of my friend Thomas Petzinger, Jr, now CEO/chairman of LaunchCyte – a technology transfer and venture capital firm, then a Wall Street Journal reporter.

“Forget the merger of the Web with TV, of phones with computers. The most powerful convergence underway today involves silicon, the substrate of computing, and carbon, the substrate of life.”

Above all, Pharma Futurology is a positive outlook that we hope will inspire and excite you in the same way that it has for us. We look forward to connecting with you before too long.

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Pharma Futurology endeavours to provide a bird’s-eye view of the pharmaceutical industry, and where it might be in a decade’s time: how pharmaceutical firms will be connected to the wider healthcare ecosystem, and what technologies will glue it together. This information will help companies plan their strategies, so as not to be left behind.

There are a lot of pressures on the pharmaceutical industry as it stands. These are not new circumstances and their effects are already resounding around the industry. For example, the public perception of pharma is poor, with fewer people rating it positively than other industries such as banks, airlines and even life insurance. Share prices are down across the board and pharmaceutical manufacturers are suffering compared with other sectors. Internally, the picture is no better: drug development pipelines are thin, and not sufficient to replace the billions-of-dollars-worth of blockbuster drugs that are coming off patent. Mergers and acquisitions are not having the impact on efficiency and top lines that they are promising.

These issues are set against a backdrop of a changing world. The public and governments across the world are pushing for a more transparent pricing process, to get more of the drugs that can help out to the people who need them – who are not necessarily the ones who can most afford to pay. The population is ageing, and the nature of the diseases that need treating and the way in which we care for these people is transforming. Companies that insist on remaining on their old trajectories may miss the target. What is needed is a new way of thinking to stay ahead of the curve, to be proactive not reactive.

Disruptive technologies
A lot of the drive for change between now and 2016 will come from the new electronic and medical technologies that are in development at the moment. Faster and more powerful computers will provide a lot of the impetus, enabling researchers to perform more calculations and tackle more demanding problems in silico. Like the airline industry, more design and testing – eventually even clinical testing – will be done virtually.

In parallel, the global communication network will connect everyone and allow the instantaneous and secure sharing of information. Patient records, drug development data,
messages, ideas, instructions and many other things can be transmitted around the world so that people do not have to be.

Facilitated by this communication overhaul and new electronic capabilities, nanometre-sized technologies will permit non-invasive, continual monitoring of people’s well being. Unobtrusive, passive sensors are already being fitted into the homes of vulnerable, elderly people that can alert the appropriate help when a problem is detected. Further into the future, these sensors will be routinely worn in clothes or even incorporated into the human body – sprayed onto the skin or implanted just under it.

New medical therapies will be based on advances in our understanding of genes and other molecular biomarkers. Knowing how different people react to the same medications will permit the development of more efficacious treatments with fewer side effects. More medicines will come with their own diagnostic test, heralding the start of true evidence-based medicine and personalised treatment.

This future is not a million miles away; much of it is here today. You only have to look around you.

Impact on pharma
The patient will be more connected to the healthcare network, yet at the same time less inconvenienced by it. The medicines patients take will be better suited to their needs, and their response to it will be observed. This will require pharma to communicate with doctors and other healthcare providers to gather more in-life data and to connect with the real end-user – the patient.

More efficacious, specialised drugs can command a higher price, but on the other hand a drug that does not work will not be reimbursed. Outcomes-based payment will keep pharma on their toes while reassuring healthcare payors that they are providing the best treatment they can.

Targeted therapeutics and associated diagnostics developed with the help of powerful computing technology will require smaller clinical trials and be faster and cheaper to bring to market. The resulting reduction in the importance of the blockbuster model need not mean lower pharma incomes.
New ways of working can lift innovation and bring investors back to the fold. Coupled with the new global development chain, there is ample opportunity for pharma to restore profit margins and public support.

If it continues to operate in the same way that it does today, the pharmaceutical industry risks becoming isolated from the rest of the healthcare network, and being forced to accept changes to its way of operating. In order to avoid this scenario, drug development companies need to play a leading role in improving all nations’ health and well being. This requires them to act now to modify their strategies and make the right connections: to physicians, regulators, governments, payors and – most importantly – the patient. It is a joined-up network, and pharma need to find their place within it.

“If it continues to operate in the same way that it does today, the pharmaceutical industry risks becoming isolated from the rest of the healthcare network...”
Futurology – the study of the future – involves critical reasoning about the way things will develop based on observations of the present, while considering the path that development has taken to get to this point.

It is no easy task to predict the future. Throughout history some of the biggest brains have tried and failed. Literature is littered with examples of poor predictions (see ‘Prediction vs Outcome’). For instance, in 1977 Ken Olsen, President and co-founder of Digital Equipment Corp, said: “There is no reason for any individual to have a computer in his home.” A statement now laughably inaccurate. Preparation for the future, however, does not necessarily need accurate prediction. Marshal the facts, analyse potential outcomes, set your strategy and you will be able to plan for the future. It is by far a greater mistake to witness change and to ignore it completely.

The latter part of the 20th century saw computing power proliferate; it has been said that the 21st century will be the age of biology – or more precisely biotechnology. The human genome has been mapped and the infrastructure exists or is in development to permit billions of physiological data to be collected and transmitted wirelessly, instantaneously and securely across the world, promising a revolution in the way we monitor and maintain everyone’s health. We have new ways to measure minute corporeal transformations, we are gaining the understanding as to what they mean and we are developing the technologies to translate them into diagnosis, prognosis and treatment. Change is afoot.

Whither pharma?

It is time for pharma to reconnect to the rest of the healthcare system: the network of drug and diagnostics developers, healthcare providers, healthcare workers, payors, regulators and – crucially – consumers. If the status quo remains, the risk is that the pharma niche could become isolated from the rest of the healthcare ecosystem. In the past the reality was that pharma sold to, and targeted all their marketing and educational efforts towards, the prescribing physician. Yet the ultimate consumer is the patient; physicians may prescribe medication, but it is the individual who needs the treatment and advice and who will both enjoy the benefits but perhaps also suffer the consequences.
The current state of the pharmaceutical industry is far from ideal. There are numerous pressures on the healthcare ecosystem at present, which are elaborated over the next few pages. As Dr JP Garnier, the CEO of GlaxoSmithKline (GSK), commented in 2006: “From 15 pharmaceutical companies that are important today, only a handful will probably survive.” Which will be the chosen few is not yet decided. What is certain is that continued inaction will guarantee consignment to the history books.

Pharma need to integrate with the healthcare system, engage in constructive dialogue and regain consumer confidence. Cause and effect: it is one big network and no-one can stand alone. The world is becoming a smaller place with even the farthest reaches linked to each other through new wireless technology and cheaper, faster computers. In order to join in this joined-up revolution requires some serious joined-up thinking.

Prediction Outcome
In the long term, gene-based therapies are expected to offer the greatest opportunity. The gene therapy market is projected to be worth US$12 billion by 2007 and US$45 billion by 2010.1

By 2010, the conventional mass-market blockbuster will dwindle in importance as other product types take off.2

Prediction
From 2000 onwards, the ageing and longer-lived baby boomers will be the two major demographic trends driving the pharmaceutical markets.1

Outcome
Age-related conditions such as osteoporosis, arthritis and dementia have come to the fore. Higher lifestyle expectations have also stimulated new markets such as obesity, acne and erectile dysfunction.

By 2010, multiple product types, including targeted solutions and high-density products, are expected to capture the market. There will also be an increase in targeted treatment solutions for patients with particular disease pathologies and molecular marker profiles.2

Outcome
In 2006, 182 companies worldwide were involved in developing gene therapy, up from 44 in 1995. As of 2006, there was only one approved gene therapy product: Gendicine (marketed in China since January 2004).

Although pharma relied on single product types until recently, multiple product types are now emerging. Companies are producing targeted treatment solutions to address the issues of adverse drug reactions, high R&D costs and increasing time-to-market.

Revenues from existing blockbusters are highly exposed, with a very large number of top-selling products due to come off patent over the next few years.
Public perception of pharma is at a low ebb, below the life insurance industry, car manufacturers and hospitals, and only 5–6 percentage points above health insurers (see Figure 1). The pharmaceutical industry exists to make people better, so why does it not have a better status?

In part this is because the general public has been kept out of the loop. Pharma have always focused their attention on lawmakers and doctors. Pharma spend more money than any other industry on lobbying Capitol Hill, and views most media with disdain. Most of pharma’s marketing is targeted at doctors. They take the time to educate them on the way their product works, the developmental process involved, the particular prescribing regimens, etc. The physicians in turn have only limited time to see their patients, and consequently public perception has been informed by personal experience, by those pressure groups that do target the general public and by sensationalist headline news. Thus most people recognise pharma only as generating huge profits on the back of very expensive medication and, despite all the protracted clinical trials, still persisting with the development of drugs that fail in phase III or post-approval with harm to human health.

Drug development is an expensive, risky and time-consuming business, but does the public really appreciate that? Pharma will react to criticism but rarely make the first move to reach out positively with their message. They are not doing a good job of explaining themselves and integrating with the community, despite the fact that communication technology is developing at a rapid pace. If this situation continues unchecked, pharma may find it has no voice left at all.

**Pipelines**

The biggest, richest pharma have a portfolio of big branded drugs, each commanding billions of dollars of sales every year. However, they cannot maintain market share forever; there are growing numbers of competing branded products, and patents eventually expire to open the door to generic competition. In 2007 alone, patent expiry is expected to affect drugs worth around $18 billion a year (see Figure 2).

Big patent expiries would not be an issue if they were supported by new blockbuster approvals. For decades, pharma have
successfully operated on a blockbuster model in this way. All therapeutics were intended for use by every patient who needed them. Some small allowances were made for age or sex, but on the whole it was the same pill for all. This was very efficient for a long time from the pharma point of view, both in terms of developing and testing, and of course for marketing. Even today, many pharma are still dangerously dependent on it.

Nevertheless, the low hanging fruit appears to have gone and new small-molecule blockbusters are thin on the ground. This is compounded by the knowledge that a person’s unique genetic profile and metabolism affect the safety and efficacy of the medications that person takes, casting the very notion of a blockbuster into doubt. Dr Allen Roses, worldwide vice president of genetics at GSK, is on record as saying in 2003, “The vast majority of drugs – more than 90% – only work in 30 or 50% of the people.”

The need for a new strategy is clear. Pharma pipelines are looking undernourished with fewer anticipated phase III approvals each year (see Figure 3) and declining numbers of new chemical entities launched. Those figures are not guaranteed; even in this day and age, drugs are still failing late-stage clinical development. This is not for want of R&D spend either (see Figure 4). While it is fair to say that new genomic and proteomic-type technologies are expensive and add to the R&D bill, they do not account for the entire gap. Pharma need to improve the efficiency of the drug discovery and development process, and to significantly reduce their dependence upon the old blockbuster model.

Patient compliance
Pharmaceuticals will only work if they are taken – and taken correctly: at the right times for the duration of treatment. Failure to do so puts the patient at risk of relapsing, and in the case of agents such as antibiotics encouraging resistance.

This issue of non-compliance is more than a problem between the patient and their doctor. Patients who do not take their medication and refilling their prescription represent a huge lost market. However, with more and more medications becoming available for a greater variety of conditions, the ‘pill burden’ will only increase for most people; pharma can act to improve matters.
There are many reasons why people do not take their prescribed medication. For some it is the apparent lack of effect: prophylactic or maintenance medications, for example for hypertension and other chronic conditions, do not have an apparent immediate effect either for taking the medication or omitting it. Other medication needs to be taken so frequently and/or for so long that patients tire of it, give themselves a 'drug holiday' or simply forget. The majority of medications on the market at the moment are intended for everyone suffering from a particular condition, yet patients do not respond homogenously. One size has never fitted all. Some people simply get little or no benefit from their medication, and therefore stop taking it (see Figure 5). If pharma could improve compliance, this could represent millions of dollars of additional sales.

Pharma can attack the compliance issue from many angles:
• continuing to improve the options for delivery of medications (see ‘First-class delivery’);
• providing patients with more information about the reasons for taking their medication and the importance of compliance;
• incentivising patients to remain on their schedule, e.g. with a free ringtone or a free game download for children;
• employing new technologies to remind patients of their drug regimen; and
• creating specialised, targeted therapeutics that have fewer unwanted side effects. More targeted therapeutics may

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**First-class delivery**

Over the last handful of decades there have been notable improvements in the way in which medications have been formulated and encapsulated, for example, reduce the frequency of the drug regimen and ease pill burden. The first time-release formulation came to market in 1952: Spansule from Smith Kline & French, although it was ALZA/Pfizer’s Procardia XL for hypertension that really took off in 1989. Since then there have been many advances in oral controlled-release technologies including coatings, matrix systems, slowly eroding devices and osmotically controlled devices. Controlling the rate of drug release reduces the drug plasma level fluctuations, hence improving tolerance and minimising side effects. This in turn enhances patient compliance.

Another way to achieve the same end-point is to create dual action or combination therapeutics that target different pathways at the same time. One active compound
might work to mitigate the side effects of the other, or they might be totally independent and simply benefit from being taken simultaneously, thus reducing pill burden.

As biologics become more popular, new delivery methods will be driven by the peculiar aspects of these large molecules. For out-patient, long-term, home-based drug use, injections are not ideal. Oral delivery is hampered by the simple fact that the stomach exists to digest proteins and other biological materials, so new formulations that protect the active ingredient in the stomach, but release it in the gastrointestinal tract, will be critical.

Oral is not the only route. Transdermal drug delivery via patches has been used successfully in areas such as pain, smoking cessation and, originally, motion sickness, and are most suited to small-molecule drugs. For biologics, inhalation is a possible route that avoids these issues and gets drugs to the bloodstream very effectively, while for those medications that need to be taken daily for many years, a subdermal implant is a convenient option.

Further in the future resides the possibility that tiny computers or microchips might be held within nanometre-sized capsules within the human body, programmed to release several drugs at just the right rate for maximum therapeutic effect. Or perhaps the microchip is implanted directly into a target tissue or organ and programmed to release drugs through a biofeedback mechanism. Delivery can be individualised as much as the drug can.

Figure 6: Five-year relative weekly comparison of composite and pharma-specific indices
communication, analysts and investors are likely to think that the real reason for M&A is simply to plug gaps in pipelines, thus disguising less productive R&D programmes.

External pressures
Moving forwards, pharma face even more demands to adapt the way they operate. Demographic changes such as an ageing population will affect the types of diseases that will be important in the future. Healthcare will focus more on chronic conditions, particularly those that strike in later life. Medications will need to be carefully selected to avoid drug–drug interactions. Altogether this means that healthcare costs, if left unchecked, will start to bite.

The majority of European countries have a healthcare system partially or completely funded by the state. Many of these provide treatment and medicines free – or very heavily discounted – at the point of use. Governments in these countries therefore require a high level of proof before making medicines available, and have traditionally capped profits and/or sales rebates. Until recently the US, with its health insurance schemes, has been the exception. But even in the land of the free there are increasing pressures on prices to come down and to become more transparent. On 12 January 2007 the House of Representatives passed the Medicare Prescription Drug Price Negotiation Act, which would empower the Secretary of the Department of Health and Human Services to negotiate Medicare Part D drug prices with drug developers.

Cost pressure is also coming from employers. Health benefits of one form or another are provided as a bonus of employment by 61% of firms of all sizes, but some older firms are now facing huge health bills that could financially cripple them. General Electric, for example, provides health benefits for 460,000 employees and dependents and 240,000 retirees and dependents. A 2006 study by the Kaiser Family Foundation and Hewitt Associates found that US employer healthcare premiums had risen by nearly 90% since 2000. State health spend is likewise a concern. The largest state in Canada – Ontario – is facing the prospect of having to spend 50% of total expenditure on healthcare by 2011.

Prices that pharmaceutical manufacturers can charge are also affected by international trading practices. Parallel imports, or

**Figure 7: Amount of mergers and acquisitions in pharma sector**

grey market items, are sold back into the originating country from overseas territories that have access to them at a lower price. While in the US parallel importation is currently illegal, there have been moves to change that. In January 2007 The Pharmaceutical Market Access and Drug Safety Act was introduced to Congress, which would explicitly allow parallel imports of pharmaceuticals into the US from Canada and a handful of other developed countries. As of March 2007 the Act is with the Senate Subcommittee on Commerce, Trade and Consumer Protection and the House Subcommittee on Interstate Commerce, Trade, and Tourism. Similar legislation was passed by Congress last year, but was vetoed by President Bush. Nevertheless, the writing is on the wall: healthcare costs are spiralling, and pharmaceutical prices – which are not always transparent or justified – are being targeted.

Socioeconomic issues
It is not only prices that come under scrutiny: information and intellectual property rights are being closely watched as well. Since the completion of the Human Genome Project, genetic information has been publicly available. It is accepted now that genes cannot be patented and genomic information cannot be sold. In some quarters there is pressure to extend these allowances. Basic information on toxicology of new substances; preclinical and even early clinical data. These are all potentially non-competitive data, the sharing of which will be of immeasurable benefit to pharma and the general public alike. More information equals safer drugs and faster development. The cost of not sharing is to waste time, money and resources following doomed development pathways.

This egalitarian concept might be extended even further to cover life-saving medications for important diseases; healthcare and drug availability is increasingly being seen as a human right. Moreover, this feeling will only increase as developing countries with unmet health needs become a political force (see ‘Brazil’s answer’). These are moral and ethical principals that lead to public and governmental pressure; if pharma are not seen to accept these challenges willingly the alternative could be to force them to.

All these influences will have an effect on the entire pharmaceutical industry, which for too long has seen itself as different from other industries and sectors. The pharmaceutical
The development cycle is long, which may present different challenges from those in other industries, but pharma should still take best practice lessons and learn from the way that other industries have coped with such a paradigm shift.

If they are not careful, pharma will be made scapegoats for these international healthcare concerns and be made to carry an unfair share of the costs. This does not have to be the case. If pharma can improve their standing with the public and with governments, they will have leverage and input into the new world order. The trick is to be proactive, to make the first move, to demonstrate that they are aware and that they want to help.

Pharma Futurology is not a story of doom and gloom. The message is that the future starts here, and improvements can be made.

Brazil’s answer
Brazil has been praised for its approach to combating HIV and AIDS. It provides free antiretroviral drugs for its 180,000 HIV/AIDS patients, but cannot afford the prices charged by some large firms. In May 2007, following the breakdown of negotiations with Merck & Co, Brazil bypassed the patent on efavirenz and now imports a cheaper generic version of the drug from India. This action is supported by the World Health Organization, which rules that such a licence can be granted in a health emergency or if the pharmaceutical industry abuses its pricing. In July, Abbott Laboratories struck a deal with the Brazilian government to cut its price for Kaletra (lopinavir) by around 30%. In a difficult situation such as this, where both sides have a defendable position, negotiation is the key. What is important is the bigger picture.

As already stated, the future is hard to predict. However, windows of insight can be opened through study of the course of technological and medical development to date and extension of these lines to the future.

In 2006 BT ran a series of workshops with the aim of predicting the future as it pertains to the pharmaceutical industry. The workshop consisted of three groups, comprised of current pharmaceutical executives, former executives from pharma and the National Health Service now on BT’s staff, other BT people working with healthcare and BT’s Futurologist Ian Pearson.

Each group had a different moderator and worked on an alternative future scenario: everything continues as it is today; the future is the best it can be, with knowledge and technology making strong advances; and the future is as bad as it might possibly be – wars, disease epidemics, natural catastrophes.

Using a ‘reverse root-cause’ analysis methodology the teams worked forwards from their respective starting points and made predictions about what might happen and how the future might look. Outliers – the more wacky, provocative or least supported views – were removed. The resulting predictions were validated by a panel of experts from biotech and pharmaceutical firms, government, academia and venture funds.

The diagram on pages 16 and 17 is a graphical representation of these thought leaders’ views and the flux elements they identified.

**Technological advances**

General electronic and computing advances will drive much of the development in the technology that could potentially be of benefit to pharma. Electronic data capture (EDC) including electronic patient diaries is here now. The power available to computer users is also increasing year on year, both in individual machines and through networking options such as grid computing where complex calculations are split up into millions of small ‘byte-sized’ chunks and carried out simultaneously on many (sometimes millions) of computers distributed across the world.
Future Technologies and Predicted Trends

- **2010**
  - Partnerships with payor and sensor owners
  - In-li and Mure System-ePatie
  - Secure virtual networks
  - Complete ePedigree
  - Supply chain RFID track and trace
  - Home monitoring enabled
  - Connection of data silos

- **2012**
  - Data privacy guaranteed and standards agreed
  - Artificial intelligence: sensors, data, treatment
  - Outcomes-based payments
  - Manufacturing bases moved to India/China
  - Wearable devices

- **2014**
  - Outcomes-based payments
  - Complete ePedigree
  - Supply chain RFID track and trace
  - Home monitoring enabled
  - Connection of data silos
  - Data privacy guaranteed and standards agreed
  - Artificial intelligence: sensors, data, treatment
  - Outcomes-based payments

- **2016**
  - Outcomes-based payments
  - Complete ePedigree
  - Supply chain RFID track and trace
  - Home monitoring enabled
  - Connection of data silos
  - Data privacy guaranteed and standards agreed
  - Artificial intelligence: sensors, data, treatment
  - Outcomes-based payments
  - Manufacturing bases moved to India/China
  - Wearable devices

- **Semantic web in R2D widespread**
  - Electronic medical records
  - System-ePatie record
  - Manufacturing bases moved to India/China

**Pharmaceuticals**

- **NOW**
  - Outcome-based payments
  - Complete ePedigree
  - Supply chain RFID track and trace
  - Home monitoring enabled
  - Connection of data silos
  - Data privacy guaranteed and standards agreed
  - Artificial intelligence: sensors, data, treatment
  - Outcomes-based payments
  - Manufacturing bases moved to India/China
  - Wearable devices

**Connection of data silos**

**Data privacy guaranteed and standards agreed**

**Artificial intelligence: sensors, data, treatment**

**Complete ePedigree**

**6* Outcomes-based payments**

**3* Manufacturing bases moved to India/China**

**4* Wearable devices**

**2* Connection of data silos**

**2010**

**2012**

**2014**

**2016**

**Semantic web in R2D widespread**
In-life trials and plots

Drugs routinely tested in silico

In silico modelling plots

Shift to prevention and care

Monitoring workplace

Sensor pilots

Ubiquitous use of diagnostics

Theranostics commonplace

Prevention drugs become dominant

Outcomes data drive payments

Expert system used in primary-care setting

NICE uses outcomes and screening data

Theranostics commonplace

Ubiquitous use of diagnostics

Multimedia patient reports

System-wide ePatient records

Outcomes data drive payments

Sensor pilots

Ubiquitous use of diagnostics

Theranostics commonplace

Prevention drugs become dominant

Outcomes data drive payments

Expert system used in primary-care setting

NICE uses outcomes and screening data

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Preven
How things will change

On average, machines are getting 1,000 times faster every 10 years. This means that it will not be long until pharma will be able to practically employ molecular design and modelling and predict native protein structures to aid in the design, development and testing of new drugs. While we are seeing the start of this development now, in the next decade it will become part of the standard pipeline of drug development (see ‘In silico modelling’).

Patients’ medical records are a prime example of the type of information that will be digitally held in the future. This will allow all medical staff with the correct clearance to access all information concerning a person’s health. Not only text –

In silico modelling

In many ways the pharmaceutical industry is very primitive. It has inherited a scatter-gun way of working: it starts by looking for an interesting, active compound, then synthesises and tests it. Many new biotech companies follow the same approach, despite claiming to be different. This ‘cookery’ methodology has several drawbacks, not least of all its heavy reliance on luck. No other industry works this way.

“If Boeing developed aircraft the way the pharmaceutical industry develops drugs, they would develop 10 very different aircraft, fly them, and the one that stayed in the air would be the one they would sell.”

Tom Paterson, Chief Scientific Officer, Entelos, Inc.

If pharma took its lead from the airline manufacturers, it would be able to design and test new compounds in silico; not generating physical candidates until they were 99% sure they would work, and only testing the surest hits in people.

There are different ways that in silico R&D – or predictive biosimulation – will aid the drug discovery and development process:

• Target identification and validation could be improved by using models of disease pathways to find suitable intervention points, then exploring what happens when these pathways are modulated. Progress in genetics coupled with in silico computing will eventually mean that it will be possible to move from genetic code to protein composition, configurations and even to post-translational modification and other additional transformations.

• Lead optimisation and candidate selection will become more of a science than an art, replacing non-human in vivo technologies and isolated in vitro assays with in silico models.
notes and prescriptions, etc. – but eventually multimedia files such as scanned images, readings from monitors and perhaps even audio and video recordings (see ‘Data spine’).

Collecting, storing and retrieving information is the first phase of the digital society; next is actually being able to make sense of it through analysis, pattern identification and even forecasting. With so many data, the way to do this is through advanced computer programs and eventually artificial intelligence. By automatically trawling through the information landscape, subtle signs of problems can be spotted to facilitate earlier diagnoses.

This is analogous to the way that the millions of webpages are indexed on the World Wide Web, and will be indexed in the future. In the next decade, semantic analysis will come to the fore. This is a logical but diffuse natural language search that joins associated concepts, even if they are held in different formats in separate parts of the Internet across the world. Data silos will be linked. The link between people and computers will be improved, helping to avoid duplication of effort. This is more than knowledge management, it is gathering of wisdom.

Related to computing advances is communication and data distribution. Connectivity, wireless interface (wi-fi) and secure

By being able to quickly and accurately move from primary protein structures to tertiary structures, lead candidates can be designed to fit perfectly into the correct pockets in a high-throughput fashion.

- **Clinical development** can also be simulated using virtual cells, organs, limbs or even whole patients, thus allowing earlier identification of ineffectual or toxic compounds and reducing the risk to the eventual clinical trial subject. Coupled with population genomic information, applied in silico technologies will therefore move from the lab to more ‘real-life’ situations, predicting the results of whole trials in different populations. Any trials that do eventually take place in real-world populations can use this information to modify their protocols and thus improve their chance of success.

Failure prediction in drug development is just as important as success, and the sooner this can be done the better to prevent wasting time, money and resources. This is perhaps the most powerful application of in silico technologies. Late-stage (phase III or post-approval) drug failures will be a thing of the past.

**Data Spine**

BT and NHS Connecting for Health are building the NHS Spine, one of the world’s largest transactional databases that forms the core of the NHS Care Records Service

BT has developed the systems and software to support more than 275,000 registered users, each generating some 375,000 patient traces, 50,000 retrievals for patient demographic information and 65,000 new or updated patient registrations.

BT was awarded the 10-year contract to deliver the Spine in 2003. The Spine is part of the NHS Care Records Service, which is creating an electronic care record for all of England’s 50 million+ patients. The Spine is a national, central database in which summary patient records are stored. When fully implemented, local records will automatically upload important information to the summary patient record on the Spine.
How things will change

Improved communications makes the world shrink. Ideas, data and even products and people can be transported across the globe in seconds, minutes and hours. This will help reduce the barriers to entry to all industries, and pharmaceuticals is no exception. Already, developing countries – notably India and China – are growing strong in pharmaceutical manufacturing alongside their acknowledged strengths in other areas of manufacturing. It is entirely conceivable that within the next decade they will have become areas of specialisation in drug manufacturing. Pharma need to get used to working with existing and new geographies, such as in the theoretical example shown in Figure 8. By embracing this global specialisation and encouraging collaboration, time to market can be cut.

Linked to improved communication, the virtual world will become more important. Virtual realities such as Second Life, the online world, will play host to formal as well as informal get-togethers. Training and education are already offered online, but in the future even more in the way of private networks. Security will be the crucial element moving forwards – being able to share yet also protect information, prevent corruption and keep safe from harm.
meetings ‘face-to-face’ will be possible. This will fit nicely with the need to reduce travel and hence carbon emissions. By 2016 it is vital that standards are agreed for electronic information to guarantee privacy.

Within modern electronic equipment, almost every component that can be shrunk is getting smaller. Nanometres – the scale that light waves are measured on – will become the dominant units. Instead of creating objects by the clumsy movement of clumps of atoms, they might be built one atom at a time to gradually grow a small yet perfectly formed end product. This will make available a whole host of new material properties and effects.

Smaller sensors will also be possible with miniaturised technology. These could be in the home, incorporated in clothing, or possibly even sprayed onto the skin (see ‘Active Skin’). There are two major monitoring modes that will be

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Active Skin

BT Futurologist Ian Pearson explains how we could be a lot closer to our computers in the future.

“Electronics could be ‘printed’ onto the skin. Small electronic components the size of skin cells (10 microns across) could be blasted into the gaps between cells,” he postulates. Semiconductor circuits can already be printed using inkjet printers, so it could be possible in the future to have circuits painlessly printed onto hands, arms, legs – anywhere on the body. Even faces.

There could be multiple layers of active skin. The upper layer could take the form of a polymer display using something analogous to liquid crystal display where nanoparticles line up in a localised electric field, while deeper, more permanent, layers would house components in contact with blood capillaries and nerve endings. “We could monitor blood chemistry and nervous responses for instance. These could be linked wirelessly to networks for early warning or to permit pharmaceutical control from a clinic.”

Other applications of this embedded technology range from the therapeutic – controlling administered drug doses using a smart membrane that opens on command to let medications through – to the cosmetic – changeable tattoos and make-up. And if your partner is away overseas? You might even be able to replay their touch.

Thus, in as little as a decade’s time, technology could well be skin-deep.

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Adapted from www.btinternet.com/~ian.pearson/web/future/pharmaceuticals.rtf
How things will change

In vitro computing

Most obviously, if pharma or other life sciences researchers learn how to manipulate biological assembly then it is a short step to pressing DNA or other molecules into service to compute biological conundrums. However, this sort of computer – whether biological or silicon – is still using series of 0s and 1s (or As, Cs, Gs and Ts, for example) to process information.

An analogue computer is one that uses mechanical, electrical or other phenomena to model the problem. Thus, instead of trying to write code that models the way a cell behaves, an analogue computer could actually use a cell. It would save hundreds of programming hours as well as provide more realistic answers.

“You don’t have to do things digitally in order to compute,” BT Futurologist Ian Pearson observes. Analogue computing was replaced by digital computing as electronics provide more consistent results in the longer term. However, advances in engineering make it possible to build analogue computers with highly precise and durable parts that will rival digital computers in their consistency and surpass them in their speed.

significant: watching sick people for danger signs, but also following healthy people to build up out knowledge of what is ‘normal’. Without a baseline normality index, how will drug developers and other healthcare players know what they are aiming for?

Finally, computers themselves will change. Today, all computers are essentially identical. They are digital machines, accurately replicating series of 0s and 1s and following binary programs that try to model real-life situations. But for more specific, messy organic tasks they could evolve into different computer phyla be that quantum, biological or, says Ian Pearson, revisiting analogue (see ‘In vitro computing’).

Medical advances

Arguably the biggest leap forwards in the biological sciences in the past decade has been the completion of the Human Genome Project. All three billion base pairs and 22,000 genes have been sequenced. The next step is to make sense of it, to understand how to get from genome to phenome; from gene to disease, including all the proteins, enzymes and metabolites in between.
Modern medical research is already making use of biological and genetic markers such as single nucleotide polymorphisms (SNPs) to detect changes and differences between samples in pharmacogenomics. One example of current use of these markers is in determining whether an individual with breast...

Personalised medicine

Despite the huge advances in knowledge of biomedical science and the human body over the past couple of centuries, there is still plenty of educated guesswork in medical diagnosis.

To move truly towards full knowledge, so-called evidence-based medicine, the most crucial step will be developing sensitive, portable, fast diagnostics. For example, a doctor will take a (non-invasive) serum sample from a patient, run it through a device in their office with minimal preparation, and read off the results within minutes. This will indicate the problem afflicting the patient, and suitable treatment can be prescribed. Initially there will be many diagnostics for different disease states, but eventually more general devices can be envisioned.

Coupled with the development of ubiquitous networks, certain diagnostic and monitoring devices can be incorporated into clothes or the skin to continually monitor physiological responses and inform or even enact pharmaceutical choices. This will be crucial in acute situations such as heart attacks where there is a small window of time for the best medications to be administered. Such a device could inform an emergency medical team about the nature of the condition, who would then be able to prepare and give a life-saving agent such as tissue plasminogen activator. Alternatively, for patients whose medical condition is known and who are at risk of an acute attack, for instance with diabetes, such a device could contain a supply of medicine protected by a membrane. When the patient’s glucose levels rise above normal levels, the device would sense this and open pores in the membrane to let a measured dose of insulin through.

In 2005, the FDA released final industry guidance addressing the submission of pharmacogenomic data, indicating that this is a serious area of concern for the agency.

Linking therapy and diagnostics – the ‘Herceptin model’ – has been termed theranostics. Whether it is a biopharmaceutical firm that develops the diagnostic test in parallel with the new drug such as Roche or Abbott, or a specialised diagnostics firm that then partners with the drug developer, is unclear. There is room for both. However, what is clear is that diagnostics will eventually take much of the guesswork out of diagnosis.

cancer has a specific receptor on their tumour that will respond to a given treatment, e.g. Roche’s Herceptin® (trastuzumab). The ultimate goal is to be able to take samples from a human, and not only predict what might go wrong in the future – what illnesses or conditions are being incubated – but also then determine the best therapy for that specific person (see ‘Personalised medicine’).

One immediate benefit of the Human Genome and Proteome Projects is the rise in the number of targets that drug developers now have to play with. Almost all the drugs currently on the market are targeted to four receptors; nearly half to just one type – the G-protein coupled receptor. Opening up the molecular space for intervention will be like a musician suddenly being presented with a full piano keyboard, having previously had only a triangle to play. Not only will the full 88 notes be available, but there is now also the option of chords. After all, most diseases are multi factorial. This should permit more powerful drug development.

But medicine is not only about curing illness; increasingly it is about preventing it – an area that few pharma have so far investigated. The impact of new technologies will be felt here too. Using the wearable devices and active skin mentioned earlier, we can start to gather information about what is healthy, but it will be a long time before the ideal or even normal genome and proteome are discerned. However, incremental steps are even now being taken. Within the next decade it will be possible to recognise someone’s predisposition to a certain condition and recommend lifestyle and even pharmaceutical choices that will mitigate that risk.

The upshot of this plethora of biomedical knowledge is that expectations of pharmaceutical treatments will be higher. This is already happening as the regulatory authorities and the general public now accept less risk than they used to. By 2016 they will accept less failure. Drugs that do not work will not be paid for (see ‘NICE choices’), thus bringing pharma more in line with other industries.

There is a further area where medicine and technology collide, slightly apart from pharma’s traditional modus operandi but one that will grow increasingly closer: bone and tissue regeneration – regrowing or replacing limbs, joints, organs and other body parts.
Prosthetic limbs will increasingly need ‘wet-ware’ connections to nerve, muscle and bone and may well have an electronic brain, linked wirelessly to monitoring and control centres. Replacement hips and other joints are already getting special coatings of biocompatible and/or pharmaceutical agents, and technology is moving ahead in the fields of ‘test-tube organs’. The pharma of the future has the potential to be more than just drugs – it can be a whole health and wellness provider. That is what joined-up healthcare is all about.

NICE Choices

In a UK first, in June 2007 the National Institute for Clinical Excellence (NICE) accepted a proposal from drugmaker Janssen-Cilag that multiple myeloma patients in Wales and England will get its treatment Velcade on the NHS, but that no charge will be paid if they fail to respond to it.

Velcade costs around £18,000 per patient, and NICE had initially indicated it would not make the drug widely available through the NHS. However, under these terms patients showing a full or partial response to the drug after a maximum of four treatment cycles would be kept on it, funded by the NHS. Patients showing minimal or no response would be taken off it and costs refunded by Janssen-Cilag.
Having examined the disruptive technologies we can now get an idea of what the future might look like for the whole healthcare ecosystem, and moreover what pharma’s place will be within it.

Commoditisation: in much the same way that our food and energy requirements are met on a daily basis, so too – eventually – will our health needs. An efficient, well-informed network of organisations and individuals will unobtrusively monitor and maintain our well being, with emphasis on the individual helping themselves as well.

By 2016 we will start to see the seeds of this new joined-up healthcare system. Before long, hospitals, general practitioners/physicians and clinics will be connected electronically, enabling universal access to medical data and resources. Universal communication access will facilitate tele-health, letting patients communicate remotely with their physician. In many cases, trips to hospitals and clinics can be avoided.

Monitoring and sensing technology will allow people to keep their independence for longer and avoid the need for nursing homes. For example, older people at higher risk of falling or exacerbating an existing condition can choose to have passive sensing technology installed in their homes that will automatically raise an alarm should any untoward changes occur to their daily pattern (see ‘From Big Brother to Big Sister’).

Communication and monitoring technologies will also have an impact on clinical trials for new medications. Already EDC, including electronic patient diaries, are speeding up data collection and improving data quality for clinical trials, but eventually these could be supplanted or supplemented with wearable devices that can record physiological responses of subjects in trials, removing the need for them to visit the medical centre. Not only will this help with recruitment and retention of subjects, but investigators too will have an easier job. In-life trials will provide a more accurate and sensitive measure of a drug’s effect.

Thus the range of medications at the doctor’s disposal will be greater. There will be a stronger, larger arsenal of drugs more aligned with the individual’s need – initially prescribed based on an individual’s genome but eventually prescribed on a
From Big Brother to Big Sister

Allowing sensors and monitoring equipment into your house may sound rather Orwellian, but nothing could be further from the truth. Passive sensors that record movement and/or temperature, for instance, are a far cry from CCTV cameras, and with data collected and analysed using algorithms there will be no prying eyes.

The benefit of allowing a small intrusion such as this into your house is immeasurable, particularly for an elderly person who might otherwise have to move into a care home.

This idea is being trialled in 20 homes in Liverpool. The tele-care project aims to assess a system that responds to crises in the home.

Each home has 12 wireless sensors, including those that monitor infrared, the entry switch, occupancy, temperature and even the flushing of the toilet. The sensors are connected to a central gateway through a secure broadband channel.

The gateway hosts specially developed algorithms that build up a behavioural model of individual activity – daily routine, habitual movements, etc. If a person falls or suffers an incapacitating problem, i.e. there is atypical activity, a data flag is transmitted over the network and a voice call is made using voice recognition technology. If all is OK, the data flag is removed.

If the cause for concern is not cancelled, however, the system sends an alert to dedicated personnel who can then use a standard web browser to access information about that person and their circumstances, and summon physical help if it appears necessary.

tailor-made basis – all employing pharmacogenomic tests. Patients receiving these medications will feel their particular needs are being more correctly addressed, and they will have more knowledge at their fingertips, thus helping to improve compliance and persistence.

There will be more emphasis on individuals taking care of their own health, helped by their employers, government, physicians and society in general. There will be incentives for people to take more exercise, eat healthily, be compliant with drug regimens and avoid bad habits.

Impact on pharma

It is shaping up to be an interesting future for pharma. There is a real chance for companies to make a difference and improve
countless people’s lives. However, it will involve a change to the status quo.

The supply chain will become quite complicated and a lot more integrated with the end-user – the patient (see Figure 9). This will have an effect on the way that pharma market and sell drugs. Medications will be prescribed in a much more formal manner based on the outcomes of diagnostic tests, with less option for doctors’ personal choice. Payment will no longer be determined simply by the number of units delivered, but will be variable depending on the success of the products.

As blockbusters are replaced by tailored medications, pharma will also find that they will have to narrow their portfolio and focus on fewer speciality or niche areas. Each disease pathway or target might yield many different drugs, all variants of each other for different genotypes.

Thus clinical trials will be smaller – yet at the same time larger. Each product will only be tested in a sub-group of disease sufferers, and with the backing of more shared knowledge, extensive in silico testing and better monitoring, will also be safer and thus the trials shorter. Instead of full approval at the end of the clinical phase, a product may receive conditional approval, with many years of follow-up required before it is totally accepted. Thus products will be faster to market allowing a quicker return on investment.

Globalisation will have a tremendous impact on pharma. The drug development process will be split into different components around the world, depending on areas of speciality. This will help improve efficiency of the process, but will bring with it the increased need to guarantee security, both of data and supply chain. Once again, electronic monitors and radio-frequency tags can help keep track of products and ensure that necessary environmental conditions (e.g. cold storage) have been met. Pharma will have a responsibility to guarantee the pedigree of its products beyond the factory gates.

Thus pharma will be a crucial player in the healthcare ecosystem – working closely with diagnostics companies, healthcare payors, international contract research and manufacturing specialists and regulators to ensure that the best treatment reaches as many people as possible for the right price.
Innovation and technology in the fields of IT, medical diagnostics, remote sensing, multimedia and ‘smart’ semantic analyses enable fully joined-up healthcare. There will be closer, stronger links between all the species in the healthcare ecosystem, including pharma. It will be the reaction of the ultimate consumer – the individual – that will determine outcome and reward. This highlights the need for a fundamental change in the way medicines are developed, assessed, delivered and paid for. Pharmaceutical companies have to participate in all facets of this transformation in order to guarantee future success.

Technological improvements will open the door to new opportunities, but they alone cannot determine whether an organisation will be successful. There is a great deal of difference between information and wisdom. It is one thing to comprehend the changes that are likely to occur, but another thing entirely to be prepared to implement them. Pharma must take positive action and start the ball rolling, as to do nothing is to run the risk of becoming mute in a networked world of communication.

Emerging markets both at home and abroad can be perceived as a threat if they are not recognised as an opportunity; early movers who proactively devise ways to work with new entrants and new technologies will gain the most. There are new cultures and populations becoming integrated in the global consciousness every year, and in order to work with them it is vital to understand them. Differences between countries and cultures can be complementary: we all have our strengths and weaknesses, and comprehending them will reveal new opportunities for collaboration.

As the world gets smaller, there will need to be structures in place to enable efficient communication and ensure compliance. Now is the time to think about these new frameworks: how best to share information, what data and with whom. There will be no ivory towers and, as the Human Genome Project opened up our DNA code for everyone to see, more basic biophysiological data will become part of the commons.

Technological improvements will open the door to new opportunities, but they alone cannot determine whether an organisation will be successful.
Pharma need to consider how they can organise themselves and establish new ways of working to ensure a seamless transition between this decade and the next. As a result of inaction over the last decade the industry as a whole has lost a lot of public trust, and companies need to work hard to regain that. Investors too are disillusioned with the current pharma model and need to see rewards from first mover behaviour, thus ensuring innovation in products and healthcare delivery as a whole.

Getting new science to market quickly and proving it works is the best way to rebuild damaged reputation and trust. Profit margins cannot be defended by putting up prices and ignoring public concerns. Communication is the key. Pharma need to concentrate on what they are best at while staying in touch with the rest of the ecosystem. Other industries have also gone through wide-ranging changes: learn from them to ensure that by the end of the next decade you are in the best position you can be.

Unlike the past, the future need not be a foreign country, as long as you put the effort in to learn the language today.

"Profit margins cannot be defended by putting up prices and ignoring public concerns. Communication is the key."
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