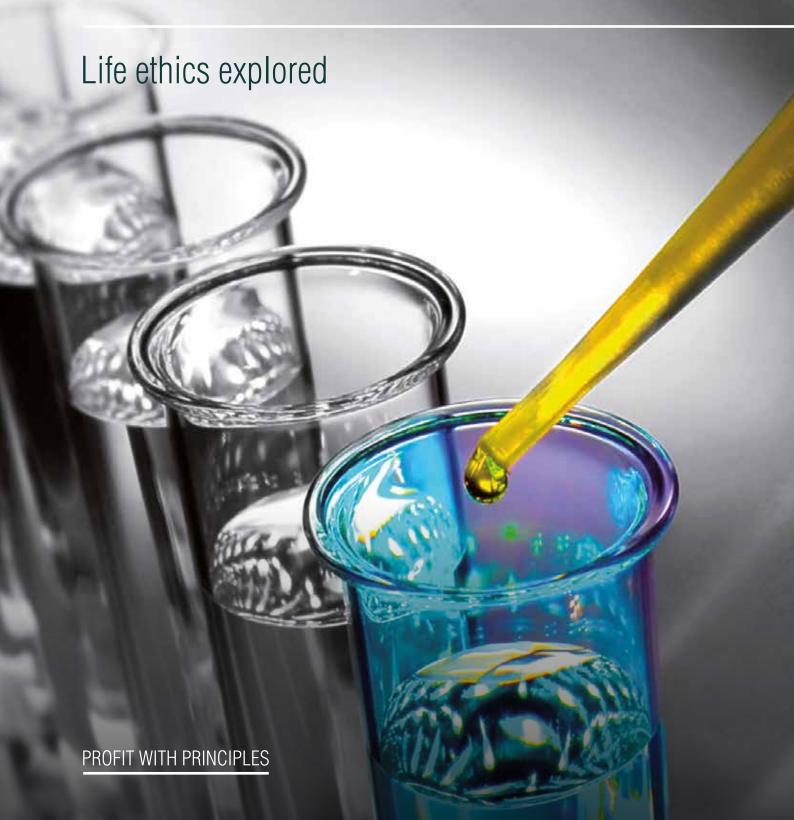
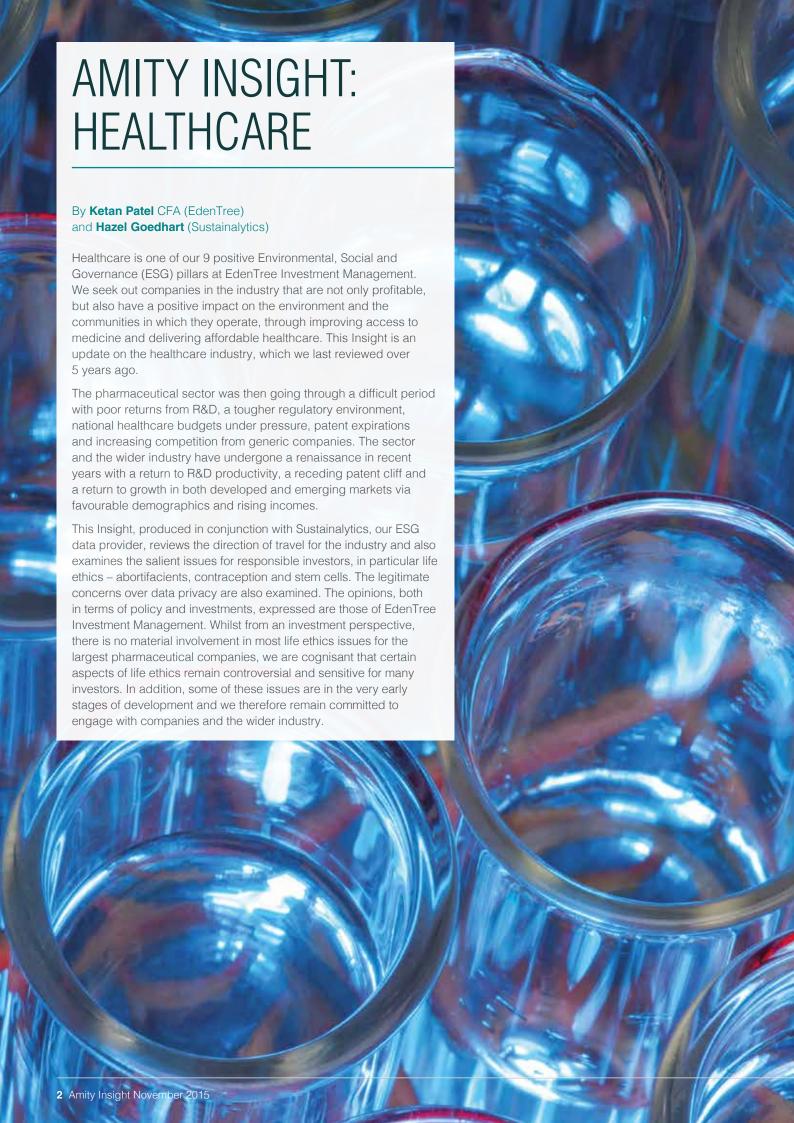


**AMITY INSIGHT** 

# HEALTHCARE:

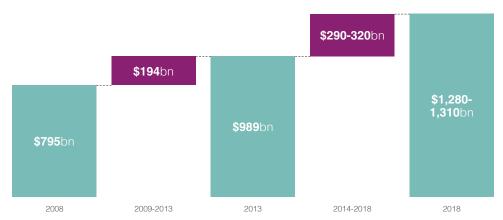




# **GLOBAL** PHARMACEUTICAL MARKET

The market for global spending on medicines is forecast to reach \$1.3 trillion by 2018, a 30% increase on 2013. The US continues to lead developed markets, followed by the 21 pharmerging countries, which are forecast to account for nearly 50% of absolute growth in 2018. China will cement its position as the second largest pharmaceutical market with spending expected to reach \$155-185bn in 2018.1 In terms of per capita, the dominance of North America, Japan and Europe will go unchallenged. In developing markets, over 80% of growth will be underpinned by generic medicines, whilst developed markets will be dominated by speciality medicines, primarily in oncology, autoimmune, respiratory, anti-virals and immunosuppressants.

### **GLOBAL SPENDING AND GROWTH, 2008-2018**



Source: IMS Market Prognosis, September 2014.

### 2009-13 GROWTH \$219BN 2014-18 GROWTH \$305-335BN 70 Absolute Growth Const US\$bn 50 40 Developed 30 Pharmerging Rest of world 10 2009 2011 2012 2013 2014 2015 -10 2010 2016 2017 2018

Source: IMS Market Prognosis, September 2014. Developed: U.S., Japan, Germany, France, Italy, Spain, U.K., Canada, South Korea.

Pharmerging: China, Brazil, Russia, India, Algeria, Argentina, Colombia, Egypt, Indonesia, Mexico, Nigeria, Pakistan, Poland, Romania, Saudi Arabia, South Africa, Thailand, Turkey, Ukraine, Venezuela, Vietnam.

# POTENTIAL FOR GROWTH

### **LONG-TERM DRIVERS**

The long-term growth of the market is driven by demographics, economic development and major health issues:

### **Demographics**

- Population growth
- Ageing population

### **Economic development in developing world**

- Strong correlation between healthcare spending and GDP
- Growing middle class
- Rapid urbanisation
- Increased access to healthcare systems 95% of the population in China is now covered by public health insurance plans

### Major health issues<sup>1</sup>

- Increase in lifestyle disorders obesity, diabetes and cardiovascular diseases. 80% of people with diabetes globally reside in low and middle income countries
- Air pollution and smoking contributing to the growth of cancer and respiratory diseases
- HIV, hepatitis and tuberculosis. Spending on oncology and HCV forecast to rise to \$100bn by 2018

### YIELD, GROWTH AND VALUATION

The pharmaceutical sector which dominates healthcare is attractively positioned, with companies offering rising dividend yields and good growth prospects, all on undemanding valuations.

### **Financial strength**

- Free cash flow yields of 5%
- Dividend yields of 3-5%
- Robust balance sheets
- Undemanding valuations

### **Favour European companies**

- Greater diversification
- Receding patent cliff
- Increased presence in emerging markets
- Relatively inexpensive valuations
- Clear ESG leaders

### Japan - structural laggard

- Constrained by regulatory environment price cuts every 2 years
- Anaemic R&D output
- Relatively expensive valuation



- 1. IMS Institute, November 2014. 2. 2014 ATM Index, www.accesstomedicineindex.org
- 4 Amity Insight November 2015

### AMITY PILLAR – HEALTHCARE Healthcare is one of the 9 positive pillars of the Amity Fund Range. We look to invest in healthcare companies, across the whole value chain, that are assisting in delivering Affordable Healthcare and improving Access to Medicine – especially to the developing world. AFFORDABLE HEALTHCARE **ACCESS TO MEDICINE** We look for companies that are helping to bring EdenTree Investment Management are signatories affordable healthcare through: to the 'Access to Medicine Index' - a biennial index, built collaboratively with ESG data provider Reducing the prices of patented medicines Sustainalytics, which ranks the largest global in less developed countries pharmaceutical companies across 7 technical Preferential pricing of vital drugs through and 4 strategic pillars. Based on the index's bestlicensing and technology transfer deals in-class approach, GlaxoSmithKline scored at the with generic companies top of the list for the fourth consecutive time in Community investment and philanthropy 2014.2 A separate SRI Expert Briefing is available programmes on the EdenTree website looking at the 2014 index results in greater detail. Examples of how Partnerships to tackle neglected diseases pharmaceutical companies have committed to e.g. malaria and ebola improve access to medicine include: • R&D investment in diseases of importance for the developing world Patient assistance programmes Patient education • Target 8e of the UN Millennium Development - Provide access to affordable essential drugs in developing countries • Innovative pricing: - Reducing taxes, tariffs and margins and developing pricing policies • R&D for rare and neglected diseases • Strengthening healthcare systems

# SECTOR ON THE MEND

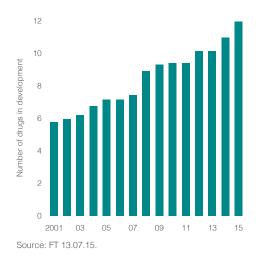
The golden age of innovation for the pharmaceutical sector was in the 1990s, which was followed by a barren period from 2000. However, the sector is very much on the mend on two fronts – a receding patent cliff and greater returns from R&D. The patent cliff, which peaked in 2012 has receded, removing a large overhang – \$37bn of sales were lost to generic competition in 2012, but this is forecast to drop to \$12bn in 2020. The industry has leveraged the sequencing of the human genome 15 years ago to develop a greater understanding of disease diagnosis and treatment. A record 61 drugs launched in 2014, compared to the annual average of 34 in the previous decade. 11 blockbuster drugs (sales of \$1bn+) are expected to launch in 2015 (up from 3 in 2014).

### FEWER DRUG PATENTS COMING TO END OF LIFE

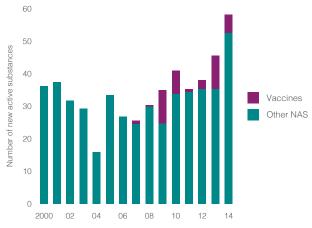


Source: FT 13.07.15.

### **GLOBAL R&D PIPELINE**



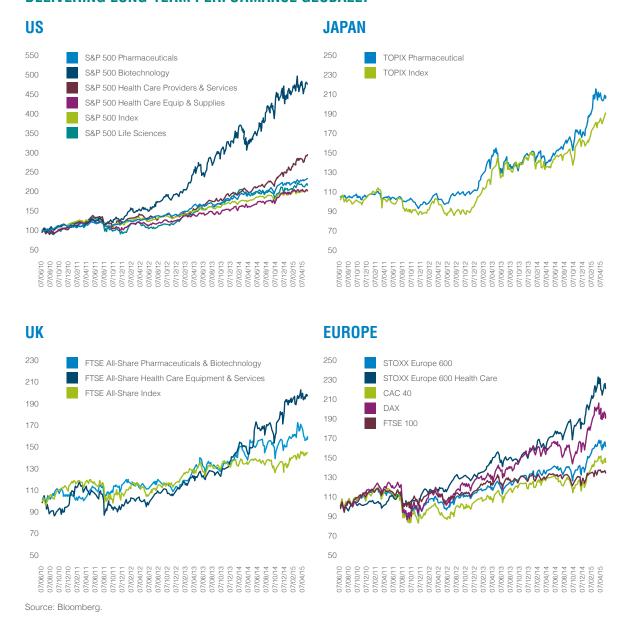
### **NEW GLOBAL DRUG LAUNCHES**



Source: FT 13.07.15.

Long-term investors in the healthcare sector have enjoyed stellar returns over the past 5 years, with US biotech companies leading the way. The US market has traditionally been the deepest and widest in terms of investment choice, but there has been a renaissance in UK healthcare, especially in the small and mid cap space. EdenTree Investment Management Funds have taken part in several IPOs and capital raises by listed companies in the wider healthcare sector. We continue to see good opportunities across all parts of the value chain in the UK and further afield.

### DELIVERING LONG-TERM PERFORMANCE GLOBALLY



# RESPONSIBLE INVESTOR ISSUES

The healthcare sector throws up several salient issues for the responsible investor encompassing business practices, labour relations, environmental management and community relations.

There are a large number of sub-issues to be considered:

### **Business practices**

Animal testing, ethical conduct in clinical trials, product quality & safety, ethical conduct in sales & marketing, lobbying and anti-competitive behaviour and data privacy

### **Labour relations**

Health & safety and human capita

### **Environmental management**

Emissions, effluents and waste and water management

### Healthcare

Access to medicines and affordable healthcare

### **Community relations**

Product donations and philanthropic activities

The sector has endured a torrid time in the last decade, dealing with global scandals across several fronts – bribery & corruption, unethical marketing & sales practices, poor data transparency, failed products endangering patients and accusations of profiteering. Whilst there is much to be critical of, companies across the whole value chain have made great strides to embrace corporate responsibility. The industry remains uniquely positioned in being not only dedicated to saving lives, but also responsible for delivering strong returns to shareholders, the economy and society.

The industry faces several challenges in the form of tougher regulation, complex markets in the developing world and new disruptive technologies. Companies which embed ESG at the core of their business models will be best placed not only to remain profitable, thereby delivering long-term sustainable returns to shareholders, but also to fulfil their obligations to society more widely. At EdenTree, we believe that via effective engagement, we can monitor direction of travel of companies, to ensure that the interests of all stakeholders – patients, healthcare systems, companies and investors – are fully considered.

We have already examined two key areas for responsible investors in this and previous Amity Insights – Affordable Healthcare and Access to Medicines. The focus of this Amity Insight is on two key areas. Firstly, life ethics examining contraception, abortifacients and stems cells and finally looking at the challenges and opportunities companies are facing when managing data privacy and security.



# LIFE ETHICS ISSUES

### **CONTRACEPTION**

The World Health Organisation (WHO) estimates the population with an unmet need for contraception is 225m women in the developing world.¹ Contraception has a vital role in helping to deliver on three of the eight targets set by the UN Millennium Development Goals – improve maternal health, combat HIV/AIDS and reduce child mortality. Access to effective contraception empowers women not only to plan families, but also to improve their education, employment and life chances.

There is still an important unmet need for contraception, especially in sub-Saharan Africa and Oceania, where only 28% and 39% of women respectively use at least one method of contraception.<sup>2</sup>

New HIV infections fell by approximately 40% between 2000 and 2013, from an estimated 3.5 million cases to 2.1 million.<sup>3</sup>

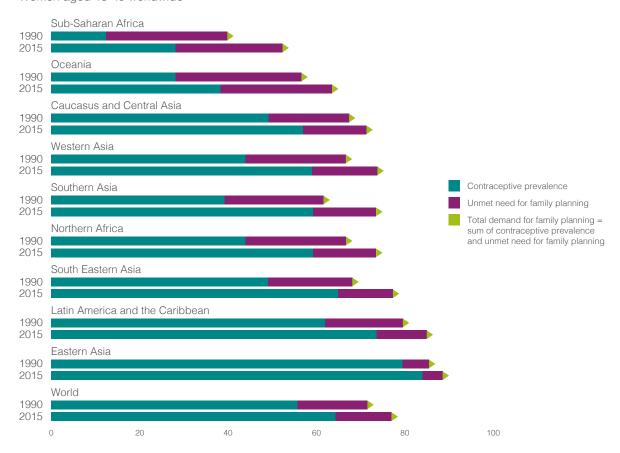
Worldwide, the birth rate among adolescent girls aged 15 to 19 has declined from 59 births per 1,000 girls in 1990 to 51 births in 2015.<sup>4</sup>

### **COMPANY INVOLVEMENT**

The largest pharmaceutical companies have a very modest exposure to contraceptives, with the space being increasingly dominated by generic manufacturers and consumer health companies.

### THE NEED FOR FAMILY PLANNING

Women aged 15-49 worldwide

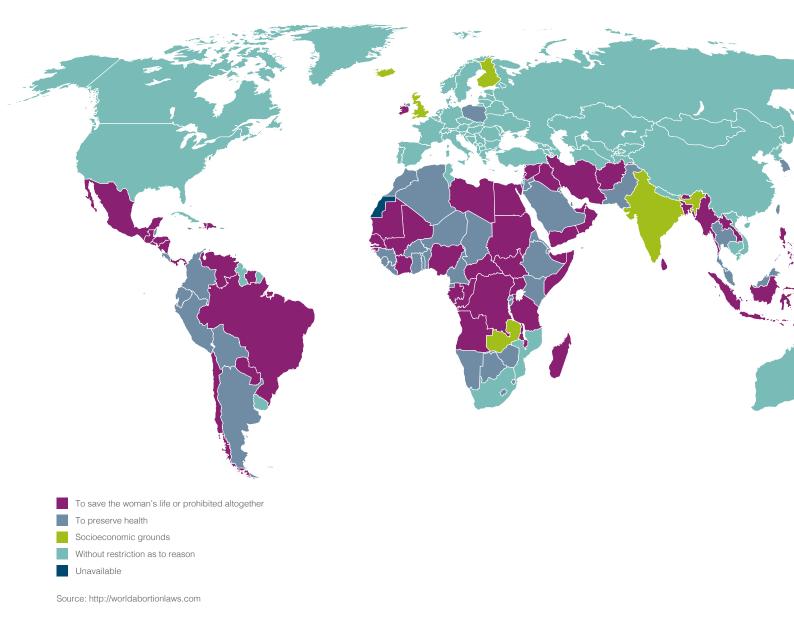


<sup>1.</sup> www.who.int/mediacentre/factsheets/fs351/en/ 2. The Millennium Development Goals Report 2015. 3. Ibid. 4. Ibid.

### **ABORTIFICIENTS**

An estimated 208 million pregnancies occur in the world annually, more than 80% of which happen in the developing world. However, more than a third of all pregnancies are unintended or even unwanted. Unsafe abortions are more likely to occur in countries where abortion is illegal, with 68,000 women globally dying from complications. However, abortion rights vary across the world as countries apply different legislation ranging from complete freedom to a total ban or only allowed in the case of life-threatening situations.

74 countries currently permit abortion without restriction as to reason.<sup>3</sup> 25% of the world's population live in countries where abortion is either specifically prohibited or allowed only if the woman's life is in danger. Six countries in Europe and Latin America ban the procedure under any circumstances. A further 13 countries have such tight controls upon abortion that for many it is an impossibility.<sup>4</sup>



1. The Guttmacher Institute, www.guttmacher.org 2. www.ohchr.org/Documents/Publications/NHRIHandbook.pdf 3. www.worldabortionlaws.com 4. UN data, quoted Independent 6 May 2015. 5. Amnesty International

### **COMPANY INVOLVEMENT**

Abortifacients are a class of approved drugs that can be used either singly or in combination to terminate a pregnancy via a medical abortion through 49 days of pregnancy.

DRUG	TREATMENTS (VARIOUS)	THERAPEUTIC CLASSIFICATION	
Mifepristone	Ending pregnancy – 7 weeks or less	Anti-progesterone	
	Hyperglycemia		
	Endogenous Cushing's syndrome		
Methotrexate	Severe psoriasis	Anti-rheumatics	
	Oncology – breast, skin, head, neck and lung		
	Rheumatoid arthritis		
Misoprostol	Start labour	Anti-ulcers	
	Induce abortions (with Mifepristone or Methotrexate)		
	Stomach ulcers		
	Postpartum bleeding		

The drugs listed above are used to treat a variety of other medical conditions – hyperglycemia, Cushing's, psoriasis, cancer, rheumatoid arthritis, ulcers and postpartum bleeding. From an investment perspective, the largest pharmaceutical companies have little or no direct exposure to this very specific area, with private and generic companies dominating a very niche market.

### **LETHAL INJECTION**

A further consideration for responsible investors arises in jurisdictions where the death penalty forms part of the judicial system and is carried out via lethal injection. Since the 1980s lethal injection has increasingly replaced more violent methods of state execution such as shooting and hanging, with Texas becoming the first state in the US to employ the method in 1982.

Until 2009 most states in the US employed a 3-drug combination for lethal injections: an anaesthetic (usually sodium thiopental, until pentobarbital was introduced at the end of 2010), pancuronium bromide (a paralytic agent, also called Pavulon), and potassium chloride (which stops the heart and causes death). However, controversies surrounding the use of lethal injection and doubts about its humane efficacy (between 1982 and 2010 7% of executions by means of lethal injection were 'botched')<sup>5</sup>, led the EU to apply strict protocols around the export of lethal injection drugs in 2011 under the EU Torture Regulation. From that time, companies wishing to export to the US had to ensure consignments could not be used in executions. The ban has led to drug shortages, requiring US states to adopt new lethal injection

methods, mostly a single-drug protocol (comprising a lethal anaesthetic or a single lethal dose of pentobarbital).

Whilst the US is the principal user of the lethal injection method, it has begun to replace existing methods elsewhere in the world. China, Taiwan, Vietnam and the Philippines are four jurisdictions where the method is now favoured.

Given the EU sanction regime, companies which might legitimately manufacture medicinal drugs otherwise used in capital punishment have strict protocols over their export lest they be used in contravention of the ban. Many companies have made public statements deploring the use of their manufactured products being used in executions, or have ceased their manufacture altogether. Companies typically tend to be smaller manufacturers rather than global listed pharmaceutical giants. EIM as part of its routine due diligence would expect companies to abide by the EU sanctions regime, and would not seek to invest in companies that deliberately exported drugs destined to be used in the carrying out of capital sentences.



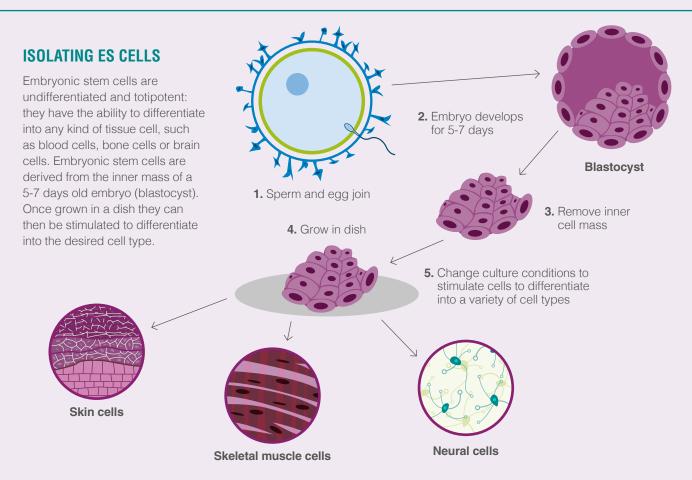
# STEM CELLS

The use of stem cells, especially embryonic, in research, remains a highly sensitive subject. The development of technology that allows embryonic stem cell extraction without destroying an embryo will help to mitigate one of the central arguments for many against the use of embryonic stem cells. Stem cells have been in use for decades in the treatment of cancers such as leukaemia via bone marrow transplants. There is, however, a need to develop a viable framework which allows for good science best practices to help develop future treatments in a wide range of therapeutic areas – Parkinson's disease, stroke, spinal cord injuries, retinal diseases, Alzheimer's and Type 1 diabetes.

### WHAT ARE STEM CELLS?

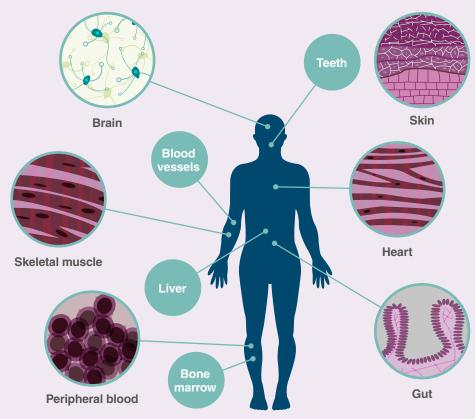
Stem cells are unspecialised cells that can proliferate or selfrenew for extended periods by dividing. Embryonic stem cells can develop into any kind of tissue and adult (somatic) stem cells can develop into specific tissue cells. The potency of stem cells can be separated into several categories:

	TISSUE GENERATION	CELL TYPE
TOTIPOTENT	<ul><li>Tissue of the embryo</li><li>Support tissue such as placenta</li></ul>	Early embryos (features are lost after a few days)
PLURIPOTENT	All specialised cell types and organs	Embryonic stem cells
MULTIPOTENT	Closely related family of cells	Adult stem cells



### **LOCATIONS OF SOMATIC** STEM CELLS IN THE BODY

Adult stem cells are differentiated and multipotent: they have already developed specific characteristics. They are derived from regenerative tissue and can differentiate into other similar cells and contribute to the renewal of damaged or dying cells in the human body. For example blood stem cells can only differentiate into other blood cells.



Source: University of Utah Health Sciences

### **HOW ARE STEM CELLS DERIVED?**

### Animal stem cells:

 Derived from mice, sheep, pigs and other animals; research conducted on mice since 1981

### Adult/somatic stem cells:

- Derived from regenerative tissue, e.g. blood, skin, gut
- Most information comes from haematopoietic (blood forming) cells found in bone marrow and blood

### Cord blood stem cells:

- Derived from umbilical cord blood
- Contains haematopoietic stem cells (HSC) rare cells found in bone marrow

### Foetal stem cells:

- Derived from aborted or miscarried foetuses
- Current foetal stem cell lines are mostly derived from tissue derived in the 1960s and 80s; these cell lines can continuously replicate, so no new sourcing of foetuses is necessary

### Human embryonic stem cells:

- Derived from the inner cell mass of a 5-7 day old embryo (blastocyst)
- Fertilized egg derived typically from in vitro fertilization

### REGULATORY ENVIRONMENT

The regulatory environment has reached international consensus on reproductive cloning (banned) and the use of adult stem cells (approved).

COUNTRY/REGION	ADULT STEM CELLS	EMBRYONIC STEM CELLS	THERAPEUTIC CLONING	REPRODUCTIVE CLONING	
United States		Limited funding support	Dependent on states		
Canada		No embryos created for research only			
EU		No funding	Dependent on member states		
Germany, Austria & Italy		Prohibited or highly restricted			
UK, Sweden, Belgium & Spain					
Switzerland		No embryos created for research only			
South Korea					
Australia					
China					
Japan					
Approved Neutral Banned					

### **COMPANY INVOLVEMENT**

Source: Sustainalytics

There are currently no approved products derived from embryonic stem cells or stem cell products on the market. Any current involvement is very much in the realm of early-stage research and we continue to monitor how companies are developing their research programmes, both in-house and partnership-based via academic and research institutions.

### **DATA PRIVACY**

Our recent Amity Insight 'Digital Planet' outlined the impact of digital technology on the healthcare sector. The rapid uptake of digital tools such as telehealth, electronic medical records (EMR) and remote patient monitoring is helping to deliver not only better care, but also higher quality care in a more efficient manner. Despite the benefits, there are also risks related to increased data availability. The healthcare sector is under increased scrutiny over data confidentiality and transfers of electronic medical records. In 2014 alone, data breach incidents in the medical and healthcare sector represented 42.5% of the 783 reported data breaches in the US.¹ Data breaches are increasingly costly. The total average cost for a company is now US \$3.8m, up from \$3.5m a year ago, and the loss of a healthcare record (\$363) is twice the average of all sectors (\$154).²

### HEALTHCARE LEADS ON A COST PER DATA BREACH PER SECTOR

Both the US and the European Commission are encouraging and promoting the use of electronic medical records. Companies will have to invest in technology and training in order to develop efficient risk management systems. In both regions companies must inform individuals about data breaches and individuals are respectively protected under the Health Insurance Portability and Accountability Act and the EU Framework on the Protection of Personal Data. Despite the risks, the digitization of healthcare offers opportunities in disease diagnosis, treatment and management. In addition, healthcare systems, which are already under considerable financial pressure, will be beneficiaries from a higher return on investment.

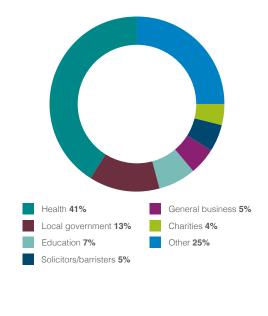
## PER CAPITA COST OF BREACHES BY INDUSTRY

Consolidated view (n=350), measured in US\$

# Dollars John Solvery Solvery

### Source: Ponemon Institute, 2015 Cost of Data Breach Study: Global Analysis

### HEALTHCARE LEADS ON DATA BREACHES BY SECTOR IN THE UK (APR 2014 TO MAR 2015)



1. Identity Theft Resource Center Breach Report 2014. 2. Reuters, May 2015.

# INVESTMENT VALUE CHAIN

At a sector level, the value chain for healthcare is the most diverse, in terms of both breadth and depth, allowing investors to build a well-diversified exposure. EdenTree Investment Management continues to maintain an overweight position in healthcare, with extensive holdings in companies in the small, mid and large-cap arena.

### **PHARMACEUTICALS**













### **MID-TECH**













### **LIFE SCIENCES**













### **BIOTECH**











REGENERON

### **HEALTHCARE**





GETINGE GETINGE GROUP







# VIEW FROM THE TOP

Our earlier Amity Insights, on Healthcare and the Pharmaceutical industry, set out our investment views and discussed some key issues for responsible investors. In this new Insight, we revisit and update our thinking. We remain positive on the sector as one of our 9 positive screening pillars, and the funds are well represented across the investment value chain. The sector is unique as it exists exclusively to support human – and animal – wellness.

Key to understanding the sector is its commitment to good science, biological and chemical, in the development of new medical treatments. This Insight considers some of the very sensitive life ethics issues that concern many investors, sometimes touching as they do on the origins of life itself and the ethical treatment of the unborn. Stem cells, in particular, hold out the prospect of significant therapeutic breakthrough in the treatment of chronic conditions, such as Parkinson's disease, stroke, spinal cord injuries, retinal diseases, Alzheimer's and Type 1 Diabetes, but as we show, there is far from universal political consensus on how this should be conducted.

We have sought to show that for the major pharmaceutical companies there is little or no direct exposure to the very specific area of birth-affecting treatments, with private and generic companies dominating, what is, a very niche market. We consider each company case by case, but would not seek investment where these treatments are judged to be a material or significant part of the product portfolio.

Stem cell research remains largely cloistered in academic institutions, tightly regulated at national and EU level, and broadly theoretical in terms of outcomes. Whilst the major pharmaceutical companies are conducting human embryonic stem cell research, this is mostly early stage, very highly regulated and with no designated products as yet. As with our general approach to new technology, we remain strongly in favour of good science and transparent peer review. We are encouraging of breakthroughs that may over time, alleviate acute suffering in previously untreatable or incurable conditions. Stem cells hold out the very real prospect of enhancing individual wellbeing and life expectations, although we remain deeply cognisant that the use of embryonic or foetal material as part of this research remains painfully challenging. We consider each company case by case, but currently there are no products near market stage, and all research remains

We hope you have enjoyed reading this Amity Insight, and as ever invite comment and feedback.



Neville White Head of SRI Policy and Research

# WHY EDENTREE?

- Over 25 years of experience of socially responsible investing (SRI)
- Funds that are both positively and negatively screened
- An investment team with a wealth of experience spanning many years
- A comprehensive in-house SRI research function
- An independent panel that reviews investment decisions
- A robust socially responsible investment process
- A pride in our independent analysis.
   We're not afraid to adopt contrarian positions and are in favour of long-term investment horizons
- A consideration of the preservation of capital as our primary responsibility, preferring absolute returns over relative performance

- Fund Managers at EdenTree are unconstrained by rigid stock lists, permitting more flexibility to take advantage of good-value opportunities as they present themselves
- Decision-making for the long term, as frequent trading increases costs and decreases returns
- Avoidance of companies materially involved in alcohol production, gambling operations, pornographic and violent material, tobacco production, testing animals for cosmetic or household products, supporting oppressive regimes or strategic weapon production
- Actively seeking out companies with a record of involvement and good performance in terms of business practices, community relations, corporate governance, education, environmental management, healthcare, human rights, labour relations and urban regeneration











# SUSTAINALYTICS



For more than 20 years, investors like EdenTree have used Sustainalytics' ESG and corporate governance research, ratings and analysis to fulfil their responsible investment objectives. Headquartered in Amsterdam,

Sustainalytics is an independent provider of ESG and corporate governance research, ratings and analytics, serving investors around the world with the development and implementation of responsible investment strategies. The firm has over 200 staff members, including more than 120 analysts with varied multidisciplinary expertise across 40+ industries. The firm partners with institutional investors, pension plans, and asset managers and for the past three years, Sustainalytics was voted best independent responsible investment research firm in Extel's IRRI survey. For more information, www.sustainalytics.com.

# **OUR PEOPLE**



cityWire AA

# Sue Round Director of Group Investments and Senior Fund Manager

Sue is the UK's longest-serving retail SRI Fund Manager. She launched the Amity UK Fund 27 years ago – pioneering our Profit with Principles investment approach. She is also AA rated by Citywire as of November 2015.



Neville White Head of SRI Policy and Research

Neville is in charge of our Socially Responsible Investing team. His extensive experience includes being responsible for managing global corporate governance proxy voting for CCLA Investment Management.



FE ALPHA
MANAGER 2015
ROBIN HEPWORTH

FUND
FUND
GUBBAL EQUITY

Rob Hepworth
Chief Investment Officer
and Senior Fund Manager

Rob has previously been voted Investment Week's Fund Manager of the Year and has been recognised as one of Citywire's top 10 Fund Managers of the past decade. This places him in the top 10% of all UK Unit Trust and OFIC Managers



Ketan Patel CFA
Associate Fund Manager

Ketan began his career on the equity derivatives trading desk at JP Morgan, before moving to Insight Investment as a Global Healthcare Analyst. Ketan leads the team's company research, supporting the Fund Managers' investment decision-making. He has been a CFA Charterholder since 2009.



citywire / +

Chris Hiorns CFA Fund Manager

Chris has worked at EdenTree since 1996. He started as a Graduate Trainee and worked as an Investment Analyst before being appointed as the Fund Manager for the Amity European Fund in 2007 and the Amity Sterling



Phil Harris Fund Manager

With over 25 years' experience in UK small and mid-cap company sectors, Phil joined EdenTree in 2015 to run the UK Equity Growth Fund. He focuses on growth small-caps and previously specialised in corporate activism.



Peter Cameron CFA
Associate Fund Manager

Analyst, having worked in both the Quant solutions and SRI performance and portfolio risk teams at Aviva. He holds a Master's degree in Corporate Governance, and is a CFA Charterholder.



Esmé van Herwijnen SRI Analyst

Esmé holds a Master's degree in Sustainable Business from Toulouse Business School and gained experience in ESG research from Sustainalytics and PIRC. She supports our SRI team with company screening, proxy voting and engagement.

### How to contact us

We hope you have found this Amity Insight interesting and useful. If you have any questions, or would like to know more about our responsible investment, in-house research and analysis, please get in touch.

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