

**The Corporate Lobbying Alignment Project -
discussion note no.2**

Investor responses to corporate lobbying & policy capture
in the healthcare sector

September 2020

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Introduction

This note is designed to educate investors on the scope, role and negative impact of corporate lobbying in the healthcare sector. It also proposes options for targeted investor responses to corporate lobbying, starting with enhanced information disclosure and moving beyond this to more assertive engagement and stewardship. Addressing corporate lobbying on public health issues will be of immediate interest for investors who have committed to support progress towards more equitable and efficient global markets and SDG 3 in particular.¹ For risk managers, the reputational and litigation risks arising from systematic mis-selling, the use of cartel-like behaviour and perceived endemic corruption in relation to drug pricing and procurement are significant.²

Coronavirus has removed any lingering doubts about the systemic nature of risk in national and global health system dysfunction. These risks extend through the pharmaceutical and medical manufacturing value chain from manufacturing sites in China and India to the structure of retail markets and procurement systems in G7 economies. Therefore, robust public policy formulation and execution free from corporate control and overt corruption in supply chains and procurement processes is important for universal investors with longer-term liability horizons.³ Alongside reputational and litigation risks for corporations, the risk of health system failure is bad for society, and bad for investors' bottom line.

Government provision of healthcare services and more robust government regulations to protect the public and users of healthcare products and services would support better public health outcomes while permitting healthcare companies to grow new business. Investors can help the industry to build more long-term incentives into its R&D, planning, remuneration, and corporate culture.⁴ Functioning public health systems and reasonable returns for private investors in listed healthcare companies are not mutually exclusive outcomes.

The world's largest healthcare companies are headquartered in the United States, Europe, and China, but their supply chains are global in nature, making their approach to lobbying important and impactful across many jurisdictions. Investors have not yet engaged in a meaningful way to address the global impact and associated risks of excessive corporate lobbying in this sector. Now is the time to do so and to remedy the most egregious elements of this policy capture problem.

¹ <https://www.un.org/sustainabledevelopment/health/>

² 'Collusion over Drug Prices: Will Generic Manufacturers Pay?' (20.05.2019): <https://knowledge.wharton.upenn.edu/article/generic-drug-price-fixing/>; Pharma chief defends 400% drug price rise as a 'moral requirement' (11.09.2019): <https://www.ft.com/content/48b0ce2c-b544-11e8-bbc3-ccd7de085ffe>; 'Novartis reaches \$642m settlement with US authorities' (02.07.2020): <https://www.ft.com/content/5f1b617d-3fd4-4e00-a2f5-9d6398806998>

³ 'Focusing Capital on the Long Term:' <https://www.fcltglobal.org/>

⁴ 'Social infrastructure, the Cinderella of the asset class' (June 2020): <https://realassets.ipe.com/healthcare/georg-inderst-social-infrastructure-the-cinderella-of-the-asset-class/10045378.article>

This note and the accompanying online dialogue⁵ are intended as a work in progress call to action, to be complemented by examples and feedback from the investment community and other stakeholders. It is the second in a year-long series of discussion notes on different sectors that will form part of a final CLAP report and online dialogue.

Summary: the cost of policy capture for investors

In the healthcare sector and other parts of the economy, corporate capture of public policy-making and regulation may skew company conduct to the short term.⁶ The OECD defines policy capture as a situation in which “ public decisions over policies are directed away from the public interest towards a specific interest.”⁷ A preoccupation with short-term, quarterly returns and shareholder buybacks reduces investment in long-term stability and growth across a number of important sub-sectors. The destabilising impacts of coronavirus have been most acutely felt in markets like the United States where the regulatory architecture of the healthcare system increasingly reflects corporate needs ahead of public health delivery.⁸ Beyond market architecture, companies may seek to use market power to inflate drug prices and profits, leading to short-term windfalls and longer-term litigation risks.⁹ Recent lobbying efforts have focused on:

- resisting government-run healthcare (in the US);
- pushing for privatisation of existing public health systems;
- increasing access to public research funds and associated tax subsidies;
- accelerating the approval process for new drugs and products; and
- strengthening intellectual property protections for patented medicines and health products.¹⁰

⁵ Register for all CLAP online roundtables here: <https://forms.gle/qxEhgQW7DbwMvxJC8>

⁶ Mckinsey Global Institute (2017) 'The case against corporate short termism:' <https://www.mckinsey.com/mgi/overview/in-the-news/the-case-against-corporate-short-termism#>

⁷ <http://www.oecd.org/governance/ethics/political-finance/>

⁸ 'How coronavirus broke America's healthcare system' (30.05.2020): <https://www.ft.com/content/3bbb4f7c-890e-11ea-a01c-a28a3e3fbd33>; and The Brookings Institute (2020) 'A dozen facts about the economics of the US health-care system:' <https://www.brookings.edu/research/a-dozen-facts-about-the-economics-of-the-u-s-health-care-system/>; and 'After Pushing Lies, Former Cigna Executive Praises Canada's Health Care System' (27.06.2020): <https://www.npr.org/2020/06/27/884307565/after-pushing-lies-former-cigna-executive-praises-canadas-health-care-system?t=1596663008936>

⁹ 'US generic drug companies hit by price-fixing claims' (13.05.2019): <https://www.ft.com/content/4688a0ea-7586-11e9-be7d-6d846537acab>; 'Why prescription drugs cost so much more in America' (19.09.2019): <https://www.ft.com/content/e92dbf94-d9a2-11e9-8f9b-77216ebe1f17>

¹⁰ <https://www.investopedia.com/investing/which-industry-spends-most-lobbying-antm-so/>

Corporate influence over the policy process

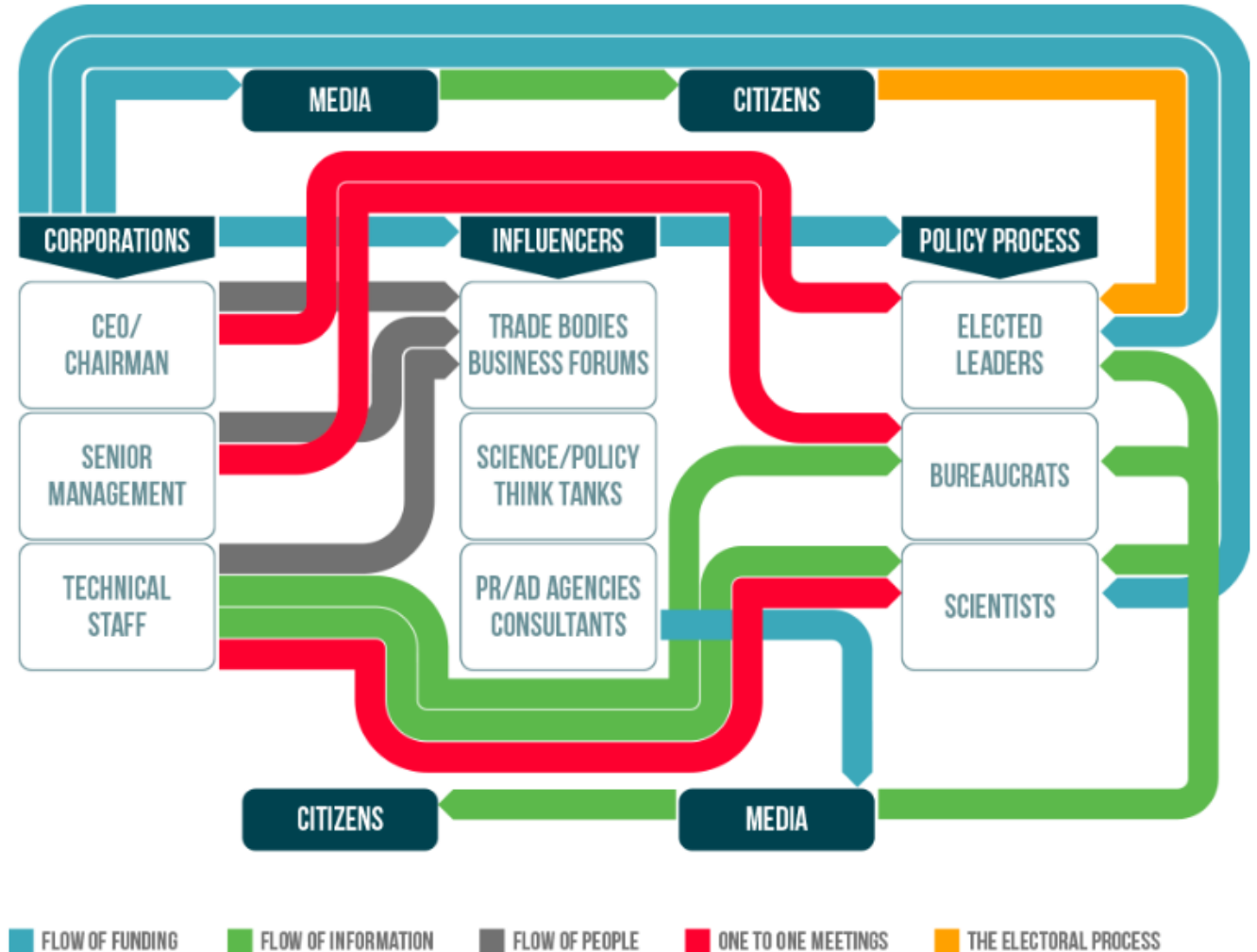


Figure 1: Investor leadership on ensuring lobbying practices in healthcare and other sectors is needed. Without assertive investor stewardship, corporate influence is able to control the public policy making process to the detriment of more efficient and transparent regulation. Source: InfluenceMap: <https://influencemap.org/page/About-Corporate-Influence>

Assertive lobbying in the healthcare sector has a long record but has grown more pronounced in the past two decades. In the United States, the 2003 Medicare Modernization Act added a prescription drug benefit to Medicare without requiring the government to negotiate bulk pricing. Instead of the government buying the drugs in bulk, companies are still able to compete on the market as providers. Friedman estimates that this legislation produced a \$242 billion surplus for pharmaceutical firms over ten years.¹¹ These short term price spikes boost profits and dividends, but long term investors should consider the implications of this pricing behaviour on the health system and larger economy. Investors should have a stronger voice on market architecture and

¹¹ Friedman JN (2009) 'The Incidence of the Medicare Prescription Drug Benefit: Using Asset Prices to Assess its Impact on Drug Makers:' <https://pdfs.semanticscholar.org/c546/293f7bde0bc8b7606ec20ffa401bb3d44175.pdf>

pricing regimes that both enable their investee companies to prosper while ensuring access to affordable medicine.

Drug pricing in particular matters for healthcare services provision, investors, and public finances. On average, Organization for Economic Co-operation and Development (OECD) countries spend 17% of their health care budgets on pharmaceuticals.¹² As a result of this, high-cost drugs - from antibiotics to insulin, can impact on the overall national budgets devoted to healthcare, reducing finances available for other important public goods like infrastructure, education and transport systems. Industry proponents argue that higher US drug prices pay for the research & development which then everyone benefits from around the world.¹³

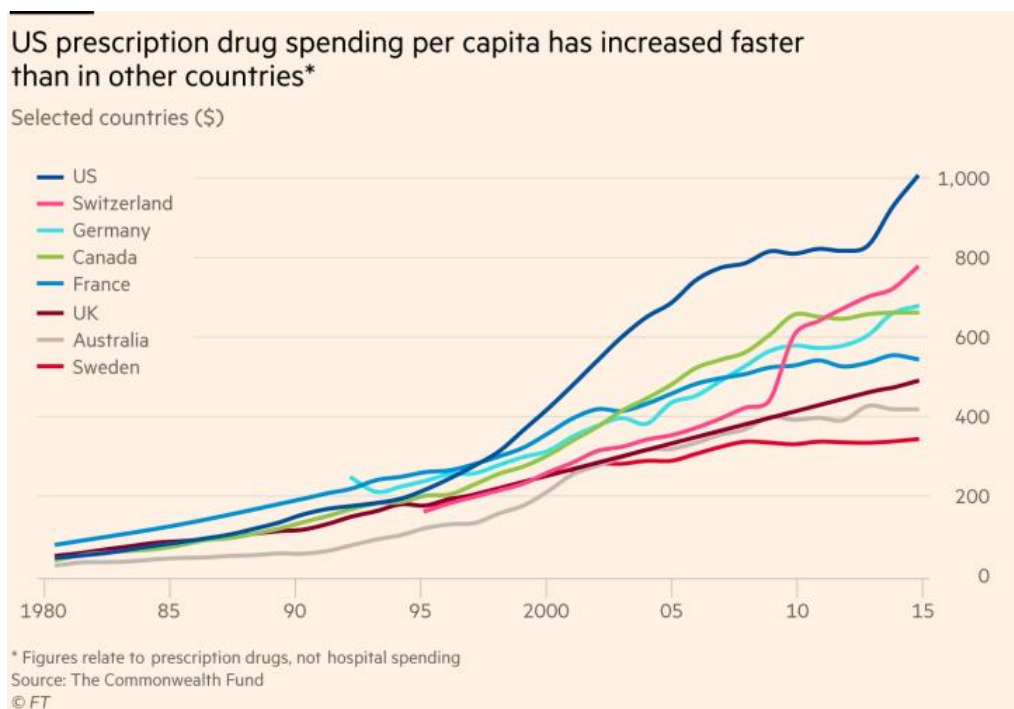


Figure 2: High prescription drug prices in the US support strong profit margins for pharmaceutical companies but may conceal other systemic risks to investors in an unsustainable business model. Chart via [FT](#).

¹² Van der Gronde et al (2017) 'Addressing the challenge of high-priced prescription drugs in the era of precision medicine: A systematic review of drug life cycles, therapeutic drug markets and regulatory frameworks:' <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5559086/>

¹³ R&D makes up a small fraction of overall US healthcare spending. Of the total United States healthcare spend of \$3.5 trillion in 2016, R&D made up 4.9% of that amount. The US federal government accounted for 22% of total R&D investment and the biopharmaceutical and their private sector peers accounted for c.65% of the \$3.5 trillion total. See: 'Report: US Medical Health Research Spending on the Rise, but for How Long?' (15.11.2017): <https://www.ajmc.com/focus-of-the-week/report-us-medical-health-research-spending-on-the-rise-but-for-how-long>. Recent research indicates that the US has average drug prices that are four times higher than in the UK, Japan, and Canada. See 'Report shows US brand-name drug prices 'highest in the world' (07.05.2019): <https://www.europeanpharmaceuticalreview.com/news/87383/us-drug-prices-highest-world/>

Defining what investor leadership looks like in the healthcare sector

Investors know what functioning health systems look like. Large healthcare investors like PGGM Netherlands operate in a country with a heavily regulated health system in which most hospitals are not allowed to make a large profit, nor to provide dividends to shareholders. The use and pricing of antibiotics in Europe is also generally better regulated than in the US and developing countries.¹⁴ The world's largest asset managers are invested globally in listed companies but also invest heavily in private markets - from hospitals to doctor services - so they understand the range of regulatory approaches, economic models and what is considered permissible by the societies whose healthcare systems they invest in. Investors should have their own guidance on what is acceptable conduct for public and private healthcare sector companies in markets where they are investing.

Prior to the coronavirus pandemic, physical assets such as hospitals, medical centres, diagnostic laboratories and other facilities that house and dispense medical and healthcare services were already considered 'safe harbour' investments. Interest in healthcare assets has ballooned following the crisis, with an expectation of large investments into public health through the recovery period and beyond. Globally, the healthcare market was worth US\$9.1trn in 2018, equal to about 10.5% of the global economy.¹⁵ The coronavirus will only make the sector more significant, increasing the scope for investor engagement and positive influence to address the most egregious lobbying conduct through the 2020s.

¹⁴ 'Fewer antibiotics in European livestock farming:'
<https://www.europeandatajournalism.eu/eng/News/Data-news/Fewer-antibiotics-in-European-livestock-farming>

¹⁵ 2020 and Beyond: Strong Fundamentals Will Keep Healthcare Deals Going Strong' (03.08.2020):
<https://www.bain.com/insights/2020-and-beyond-global-healthcare-private-equity-and-corporate-ma-report-2020/>

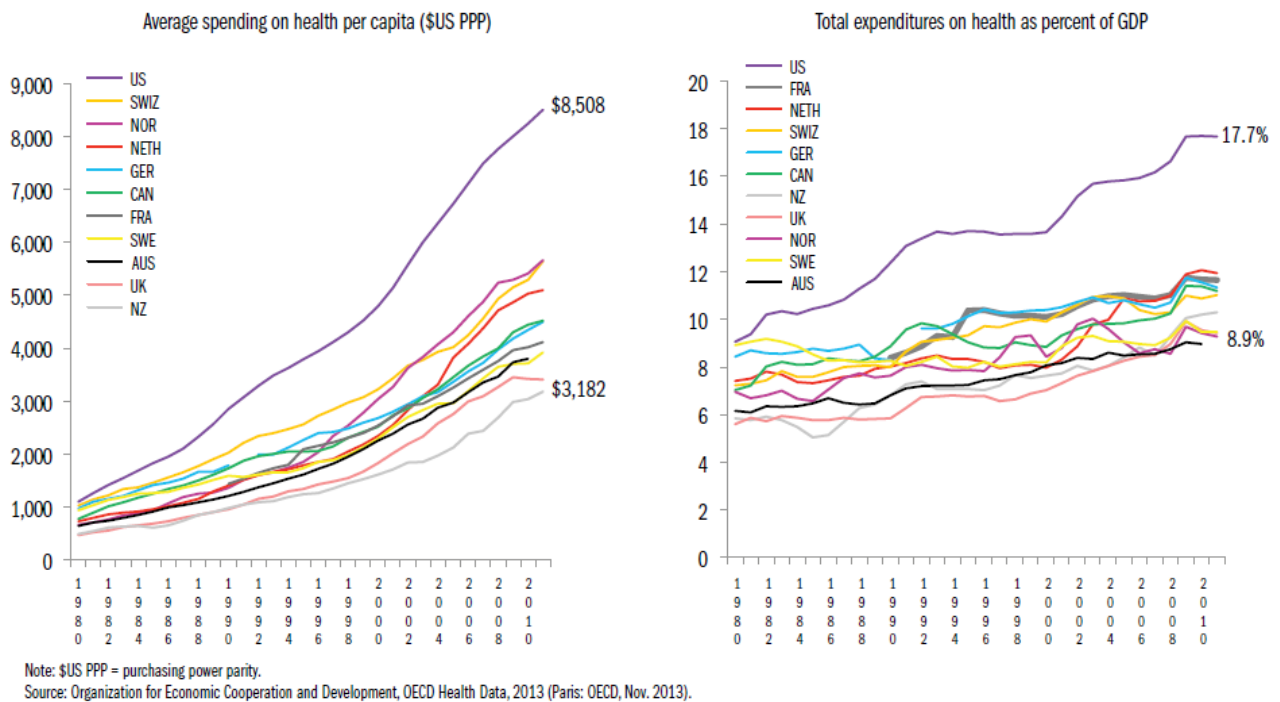


Figure 3: International comparison of healthcare spending 1980 - 2010. The cost to governments of financing national healthcare systems varies widely across the OECD. Drug pricing and the extent of company influence on healthcare system design influence these costs and have implications for other parts of the economy. Investors should be concerned about runaway health system costs that reduce funding for other parts of the economy. Source: OECD.

Lobbying to shape policy & public discourse in the healthcare system

In healthcare and other sectors, corporate lobbying is typically a response to the government's presumed agenda to protect public health and improve health outcomes and life expectancy in the most cost-efficient manner possible. Healthcare is such a wide sector that companies and their lobbying partners and trade associations work to capture a wide range of arenas of debate and decision making either because these are seen as intrinsically important or because they are useful for business activities in other arenas. In the healthcare sector, key objectives for lobbyists include:

- (a) capturing scientific expertise;
- (b) defining the role of public insurance in health systems and drug price controls; and
- (c) asserting control over the structure of a specific product market or an entire market segment.

The tobacco industry successfully muddied the waters regarding the negative health effects of tobacco for thirty years, and the healthcare sector has learned from this success. Many of the same lobbyists who supported Big Tobacco's successful refutation of modern science¹⁶ over

¹⁶ WHO 'Tobacco explained: the truth about the tobacco industry ...in its own words:' <https://www.who.int/tobacco/media/en/TobaccoExplained.pdf>. Ironically, vaping has driven a wedge between the tobacco industry and Big Pharma as the two sectors battle for market share in smoking

decades now do the same work for pharma and healthcare clients. If the science cannot be captured, lobbying strategy is likely to focus on creating uncertainty to the extent that they are able to block meaningful policy change as in the case with tobacco or on climate change.

The pervasiveness of corporate influence on health policy is such that academic literature now refers to 'commercial determinants of health'. The commercial determinants of health include "strategies and approaches used by the private sector to promote products and choices that are detrimental to health,"¹⁷ such as the promotion of opioids for off-label pain reduction. These practices led to an opioid death epidemic in the US.¹⁸ For investors, over prescription of opioids may have created short term boosts to dividends for some companies,¹⁹ but the larger economic impacts would not be positive across all sectors.

Healthcare sector companies are able to populate the information environment with a variety of seemingly independent and unconnected organisations that repeat messages that reinforce corporate interests. Industry tactics used to influence public policy, in pursuit of the aims listed above include:

- (a) coalition management - exercising influence over third parties such as health organisations, communities and the media;
- (b) information management via the manipulation of the scientific evidence base, through the funding of research, ghost-writing, and other channels to provide information that contradicts reality;
- (c) direct and indirect involvement in policy-making;
- (d) litigation or the threat of legal actions; and
- (e) PR strategies that seek to frame dominant narratives to align with their short-term interests.²⁰

cessation products, worth some €14 billion in 2018: <https://www.politico.eu/article/big-pharma-battles-big-tobacco-over-smokers/>

¹⁷ Livingstone (2020): 'Defining the commercial determinants of health: a systematic review:' <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-020-09126-1>

¹⁸ Between 1999 and 2009, both opioid sales and opioid-related deaths increased fourfold in the United States. See Psaty et al (2017) 'Addressing the Opioid Epidemic - Opportunities in the Postmarketing Setting:' <https://www.nejm.org/doi/full/10.1056/NEJMp1614972>

¹⁹ Van Zee, A. (2009) 'The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy:' <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/>

²⁰ Mialon et al. (2020) 'Mechanisms for addressing and managing the influence of corporations on public health policy, research and practice: a scoping review:' <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7371213/#SP1>; Ulucanlar et al (2016) 'The Policy Dystopia Model: An Interpretive Analysis of Tobacco Industry Political Activity:' https://www.researchgate.net/publication/308385827_The_Policy_Dystopia_Model_An_Interpretive_Analysis_of_Tobacco_Industry_Political_Activity

Engaging for change from the top down at the WHO

In response to Covid-19 concerns about overt corruption in healthcare procurement systems, demand for mechanisms to protect the policy process from undue corporate influence is growing. Investors have a key role to play in enabling reforms to corporate lobbying and disclosure regimes. Efforts at reform of international standards are longstanding. For example, in 2012, Member States requested the World Health Assembly develop risk assessment, disclosure and management tools to safeguard against conflicts of interest in policy development and implementation of nutrition programmes.²¹ The World Health Assembly is the forum through which the World Health Organization is governed by its 194 member states. It is the world's highest health policy setting body and is composed of health ministers from all member states. Investors have not yet weighed in on these issues, but institutions such as the UN-PRI could push for more work on healthcare lobbying awareness through the coronavirus recovery period and beyond at the WHO and associated multilateral standards setters like the OECD.

What does lobbying in the healthcare sector look like?

Lobbyists in the healthcare sector can channel their messages through well-established think tanks to provide legitimacy, finance academic research and use various channels to provide industry presentations to all levels of government that then influence key policy and regulatory decisions.²²

The OECD identifies “smoke screens” as one of the most common methods of corporate influence. Smoke screens are coordinated attempts to divert discussion away from the initial issue at hand as well as funding research and organisations to advance private agendas. These practices easily circumvent public and regulatory scrutiny and continue to evolve.²³ Healthcare companies may engage in this practice by using third party endorsements from patient organizations and medical experts²⁴ whose financial links to the companies are not clear.²⁵ A number of studies demonstrate how pharmaceutical companies and trade associations engage in high-level political lobbying and foster alliances with groups both inside and outside the state apparatus to influence the policies, laws and regulations relevant to pharmaceutical markets.

Off-label marketing practices are another form of lobbying that extends to many areas of the healthcare system and is particularly pervasive in the United States and Canada. Off-label

²¹ Resolution WHA65.6: World Health Organization Sixty-fifth World health assembly (2012): https://apps.who.int/gb/dgnp/pdf_files/A65_REC1-en.pdf

²² CREW 'How Big Pharma Lobbies to Keep Prescription Drug Prices High:' <https://www.citizensforethics.org/a-bitter-pill-how-big-pharma-lobbies-to-keep-prescription-drug-prices-high/>

²³ <http://www.oecd.org/corruption/ethics/lobbying/>

²⁴ 'German Government flu Expert Advising Pharma 'Lobby Group'.' October (28.10.2009): <https://www.spiegel.de/international/germany/ethical-gray-zone-german-government-flu-expert-advising-pharma-lobby-group-a-657910.html>

²⁵

marketing involves pharmaceutical companies and medical practitioners promoting uses of drugs to customers and patients that are beyond the scope of the approved use or dosage. This practice poses health risks for patients who use drugs in unapproved ways, and when carried out in a systematic manner is a pharmaceutical fraud scheme.²⁶

Recent research shows how the most common alleged off-label marketing practices also appear to be the most difficult to control through external regulatory approaches.²⁷ These examples indicate the range of practices in the sector across all jurisdictions.²⁸ The variety of lobbying practices, from sponsoring friendly think tank research to creating fake grassroots groups (“astroturfing”) and off label marketing makes assessing the full extent of lobbying difficult. This extends to policy advocacy at the international level via the World Health Organisation.²⁹

From drug distribution to medical waste - lobbying extends through the entire supply chain

Pollution from the healthcare sector’s global supply chains is largely unregulated.³⁰ It should be.³¹ Industrial pollution from Indian medical manufacturers who are contracted by nearly all of the world’s major drug companies, may fuel the creation of new superbugs.³² In spite of the well documented problem of pharmaceutical pollution in India and other jurisdictions, there are no global health regulations or agreed upon standards in place to stop this and domestic regulations are not enforced.³³ Research identifies urban wastewater as the dominant emission pathway for pharmaceuticals globally, although emissions from industrial production, hospitals, agriculture,

²⁶ <https://www.whistleblowersinternational.com/types-of-fraud/pharmaceutical/off-label-marketing/>; and <https://www.hutchlaw.com/blog/pre-label-and-off-label-statements-how-to-minimize-risk-when-making-statements-about-regulated-products-prior-to-fda-clearance-or-approval-part-1-pre-label-promotion-law>

²⁷ Kesselheim et al (2011) 'Strategies and Practices in Off-Label Marketing of Pharmaceuticals: A Retrospective Analysis of Whistleblower Complaints:'

<https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000431>

²⁸ Vilhelmsson, A. (2017) 'Pharmaceutical lobbying and pandemic stockpiling of Tamiflu: a qualitative study of arguments and tactics:'

https://www.researchgate.net/publication/319015211_Pharmaceutical_lobbying_and_pandemic_stockpiling_of_Tamiflu_a_qualitative_study_of_arguments_and_tactics

²⁹ Gulland, A. (2016) 'WHO open to “lobbying” by business:'

<https://www.bmj.com/content/353/bmj.i3134.full>

³⁰ The WHO publishes a guidance document on the 'Safe management of wastes from health-care activities,': <https://www.who.int/news-room/fact-sheets/detail/health-care-waste>

³¹ 'Medical waste & human rights: submission to the UN Human Rights Council Special Rapporteur:'

https://noharm-europe.org/sites/default/files/documents-files/1684/MedWaste_Human_Rights_Report.pdf;

UN Human Rights Council (2011) 'Report of the Special Rapporteur on the adverse effects of the movement and dumping of toxic and dangerous products and wastes on the enjoyment of human rights, Calin Georgescu:' https://noharm-global.org/sites/default/files/documents-files/1683/A-HRC-18-31_en.pdf

³² 'Pharma and the environment: pollution continues despite public pressure' (02.10.2018):

<https://www.pharmaceutical-technology.com/features/pharma-and-the-environment-pollution-trend/>;

Changing Markets (2016) 'Hyderabad's pharmaceutical pollution crisis:' <http://changingmarkets.org/wp-content/uploads/2018/01/CM-HYDERABAD-s-PHARMACEUTICAL-POLLUTION-CRISIS-EX-SUMMARY-WEB-SPREAD.pdf>;

FAIRR (2016) 'Superbugs and super risks The investment case for action:' <https://www.fairr.org/article/superbugs-and-super-risks-the-investment-case-for-action/>

³³ 'The problem of pharmaceutical pollution:' <https://eeb.org/the-problem-of-pharmaceutical-pollution/>

and aquaculture are important locally and can be addressed as part of a value chain based ESG risk assessment by investors. Like recent investor initiatives on mine tailings waste disposal,³⁴ and interest in the economics of nuclear waste disposal³⁵ and mine closure,³⁶ pharmaceutical waste should be another priority. The extent of the unchecked pharmaceutical pollution problem is one indication of how the healthcare sector's political power.³⁷ The environmental³⁸ and human costs of excessive lobbying by the sector are most apparent in the US market, so our analysis will focus there.³⁹

The opportunity for investor engagement on systemic risks in the healthcare system

As stated by the Financial Stability Board following the 2008-09 financial crisis,⁴⁰ "G20 members consider an institution, market or instrument as systemic if its failure or malfunction causes widespread distress, either as a direct impact or as a trigger for broader contagion" in the financial system and/or the real economy. The challenge for investors is to build long-term stability and a response to these systemic risks into their engagement strategies with companies and legislators in the largest healthcare markets. For the purposes of the healthcare sector, our analysis focuses on North American and European listed companies, the largest private sector participants in the global healthcare system.

Investor stewardship to enable healthcare system resilience

Coronavirus has raised the profile of systemic risks in the healthcare system and the stewardship role of institutional investors in addressing these risks. Investors in 15 major pharmaceutical companies have called on drug makers to set aside rivalries and short-term interests and

³⁴ 'Investors launch tailings database and propose principles for responsible mining' (24.01.2020): <https://www.responsible-investor.com/articles/investors-launch-tailings-database-and-propose-principles-for-responsible-mining>

³⁵ Taylor, S. (2008) 'How should investors value nuclear liabilities?': <https://jbs.cam.ac.uk/wp-content/uploads/2020/08/wp0804.pdf>

³⁶ 'It's Closing Time: The Huge Bill to Abandon Oilfields Comes Early' (18.06.2020): <https://carbontracker.org/reports/its-closing-time/>

³⁷ Lubbert et al. (2017) 'Environmental pollution with antimicrobial agents from bulk drug manufacturing industries in Hyderabad, South India, is associated with dissemination of extended-spectrum beta-lactamase and carbapenemase-producing pathogens:' <https://link.springer.com/article/10.1007/s15010-017-1007-2>

³⁸ USGS 'Pharmaceuticals in Water:' <https://www.usgs.gov/special-topic/water-science-school/science/pharmaceuticals-water?>

³⁹ 'Drug makers shell out record amount lobbying Congress' (23.07.2019): <https://www.ft.com/content/4e2932e6-ad77-11e9-8030-530adfa879c2>

⁴⁰ FSB (2009) 'Guidance to Assess the Systemic Importance of Financial Institutions, Markets and Instruments: Initial Considerations Report to the G-20 Finance Ministers and Central Bank Governors:' <https://www.imf.org/external/np/g20/pdf/100109.pdf#page%3D4>

cooperate on finding solutions to the coronavirus.⁴¹ Investors pushing for enhanced corporate governance and more transparent drug pricing regimes for the sector are challenged by the strong returns provided by the largest pharma sector companies, particularly in the United States. **Coronavirus vaccines and more transparent drug pricing should be two engagement priorities for investors.**

Stock buybacks instead of R&D

The top 10 US pharmaceutical companies' spending on payments to shareholders, including stock buybacks and dividends, increased almost 75 percent from 2017 to 2018, totalling \$115 billion or roughly 167 percent of these companies' total net income.⁴² This number was significantly higher than firm-reported spending on R&D, which totalled almost \$71.7 billion.

Lobbying in the US healthcare sector: assessing short-term opportunities & long-term risks

The growth of corporate lobbying in the healthcare sector is a natural response for companies who come to Washington, DC, and other national capitals to respond to perceived regulatory threats. Lobbyists teach corporate managers about the importance of being politically active and help focus on new influencing opportunities. The overall effect is that American businesses have become increasingly confident, proactive, and assertive in lobbying efforts in the domestic and international healthcare arenas.⁴³ The US approach to lobbying in the healthcare sector has influenced their global peers, suggesting that investors could have similar influence to improve the lobbying practices across the global health system, starting with the largest markets in Europe and North America.

Lobbying in the healthcare sector grew significantly around the US Orphan Drug Act passed in 1983, which provided pharmaceutical companies incentives to develop drugs with small markets. In the mid-1980s, there was an attempt by the pharmaceutical industry to ease bans on exporting drugs to developing countries and to reduce liability for vaccines. The next major corporate engagement event was the 1992 Prescription Drug User Fee Act, which allowed pharmaceutical companies to pay more to directly fund the national regulator, the US Food and Drug

⁴¹ 'Institutional investors tell Big Pharma to cooperate on coronavirus' (17.04.2020):

<https://www.reuters.com/article/us-health-coronavirus-investors-pharmace/institutional-investors-tell-big-pharma-to-cooperate-on-coronavirus-idUSKBN21Z1WZ>

⁴² 'Profit Over Patients: Americans are Paying for a Financialized Pharmaceutical Industry' (19.06.2019): <https://rooseveltinstitute.org/profit-over-patients-americans-are-paying-for-a-financialized-pharmaceutical-industry/>

⁴³ Rose-Ackerman & Tan (2014) 'Corruption in the Procurement of Pharmaceuticals and Medical Equipment in China: The Incentives Facing Multinationals, Domestic Firms and Hospital Officials:' <https://escholarship.org/content/qt5742d68k/qt5742d68k.pdf>

Administration (FDA) in order to speed up drug approval timelines.⁴⁴ A similar arrangement exists in Europe with the European Medicines Agency.⁴⁵

An additional piece of legislation the industry has engaged heavily on is the 21st Century Cures Act.⁴⁶ The bill, which passed the House, would encourage the Federal Drug Administration (FDA) to rely less on randomized controlled trials when deciding whether or not to put a new drug on the market. Critics argue that this would bring more new drugs to pharmacy shelves at a faster pace, at the expense of patient safety.⁴⁷ Lobbying efforts focus on the patent system, research funding and Medicare. Healthcare industry lobbying spending in the US hit a record in spending over \$270 million on lobbying activities in 2009, during the time the Affordable Care Act was being debated in Congress.⁴⁸

This lobbying activity and associated spending on political donations⁴⁹ and public relations is productive for healthcare companies as the US healthcare market is large and profitable. In total, the top 20 best-selling drugs generated over \$130 billion dollars in US sales in 2017.⁵⁰ The five drugs with the largest price increases in 2017 generated \$38.8 billion in sales.⁵¹ All five of these drugs have been on the market for more than a decade, yet none has meaningful generic competition.⁵² Investors who understand the sector are well placed to express the need for companies to balance short term profits with the long term viability of predatory pricing and the dismantling of a public health system.

Opportunities to engage in forceful stewardship in the healthcare sector

1. Investors should prepare to bring shareholder resolutions on corporate lobbying alignment in a systematic way to support systematic disclosure across the transport sector. These could be like the resolution filed at Pfizer in 2020, and be brought that the 10 largest companies in the sector by revenue⁵³

⁴⁴ 'Prescription Drug User Fee Amendments:' <https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments>

⁴⁵ 'High prices, poor access: the EU medicines market and Big Pharma' (09.05.2019): <https://corporateeurope.org/en/2019/05/high-prices-poor-access-eu-medicines-market-and-big-pharma>

⁴⁶ 'Pharma companies push hard on House bill to ease testing of new drugs:' <https://www.opensecrets.org/news/2015/06/pharma-companies-push-hard-on-house-bill-to-ease-testing-of-new-drugs/>; see EMA fees here: <https://www.ema.europa.eu/en/human-regulatory/overview/fees-payable-european-medicines-agency>

⁴⁷ <https://www.opensecrets.org/federal-lobbying/industries/background?cycle=2019&id=H04>

⁴⁸ Id.

⁴⁹ 'SEC Rule Sought on Corporate Political Money' (15.05.2015): <https://www.courthousenews.com/sec-rule-sought-on-corporate-political-money/>

⁵⁰ <https://www.linkedin.com/pulse/20-best-selling-drugs-2018-luca-dezzani-md>

⁵¹ 'With New Tax Savings, Drug Companies Start by Rewarding Shareholders, Not Patients Struggling with Skyrocketing Prices:' <https://www.fdanews.com/ext/resources/files/2018/04-10-18-Booker.pdf?1523388900>

⁵² 'Skyrocketing Drug Prices: Year One of the Trump Administration:' <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Skyrocketing%20Drug%20Prices-Year%20One%20of%20the%20Trump%20Administration.pdf>, at 5.

⁵³ https://www.iccr.org/sites/default/files/page_attachments/pfizer-proxymemo_pollobbyingdisc-final.pdf

2. Investors should ask for a global roadmap for universal health insurance coverage in line with the WHO's Roadmap for Access to be published at the G20,⁵⁴ via the Business Twenty (B20) corporate lobby group.⁵⁵

3. Investors should engage their own in-house legislative affairs teams to develop a deeper understanding of corporate lobbying practices and how to push investee companies in the healthcare sector to limit negative lobbying on drug pricing, access to affordable care and other key issues, and to ensure trade associations do the same. In the case of the largest asset managers such as BlackRock,⁵⁶ they both invest in and provide services to healthcare companies, so understand the business model and those areas where lobbying contributes to political dysfunction.

Demonstrating forceful stewardship with detailed information requests

Investors can bring simple questions into their engagement process to ensure greater transparency and communicate expectations on company and trade association lobbying activities. The three questions below may be a useful starting point for these dialogues:

1. Does your company or affiliated trade associations lobby the public health regulator [*please specify relevant agencies based on jurisdiction*] to change policy or health and scientific guidelines to benefit any one of your product lines? If so, what form does this lobbying take and is there a public record of the activities?
2. Have you or one of the trade associations of which you are a member succeeded in having any policies changed by [*insert public health body/regulator*] through lobbying that is not based on independent clinical evidence?
3. Do any employees of [*the national regulator*] receive any gifts, money, rewards, incentives, hospitality or any other type of financial benefit from your company?

⁵⁴ WHO (2018) 'Roadmap for access 2019-2023: comprehensive support for access to medicines and vaccines:' https://www.who.int/medicines/access_use/Roadmap_for_access_zero_draft_2_July_2018_FINALv1clean.pdf?ua=1

⁵⁵ The B20 is the official business community engagement forum for the Group of Twenty (G20). The B20 is run in partnership with the global accountancy trade body, IFAC: <https://www.ifac.org/knowledge-gateway/contributing-global-economy/discussion/g20-and-b20-saudi-arabia>. <https://www.b20saudi-arabia.org.sa/b20-partners/> B20 'Knowledge Partners' are Accenture, PWC, McKinsey, Boston Consulting Group (BCG) and law firm Mayer Brown.

⁵⁶ BlackRock's consulting arm has more than 80 healthcare clients, while the investment management arm has had over \$25bn in healthcare AUM as of June 2018. See: <https://www.blackrock.com/institutions/en-us/our-clients/healthcare>

		Rx Sales*	R&D spend*	Top-selling Drugs*	
1	Pfizer NEW YORK, NEW YORK [PFIZER.COM]	\$45.302	\$7.962	Prevnar 13	5.802
				Lyrica	4.970
				Ibrance	4.118
2	Roche BASEL, SWITZERLAND [ROCHE.COM]	\$44.552	\$9.803	Herceptin	7.140
				Avastin	7.004
				Rituxan	6.905
3	Novartis BASEL, SWITZERLAND [NOVARTIS.COM]	\$43.481	\$8.154	Gilenya	3.341
				Cosentyx	2.837
				Lucentis	2.046
4	Johnson & Johnson NEW BRUNSWICK, NEW JERSEY [JNJ.COM]	\$38.815	\$8.446	Stelara	5.156
				Remicade	4.890
				Zytiga	3.498
5	Merck & Co. KENILWORTH, NEW JERSEY [MERCCK.COM]	\$37.353	\$7.908	Keytruda	7.171
				Januvia	3.686
				Gardasil	3.151
6	Sanofi PARIS, FRANCE [SANOFI.COM]	\$35.121	\$6.227	Lantus	4.211
				Pentacel	2.066
				Fluzone	2.017
7	AbbVie NORTH CHICAGO, ILLINOIS [ABBVIE.COM]	\$32.067	\$5.093	Humira	19.936
				Mavyret	3.438
				Imbruvica	2.968
8	GlaxoSmithKline BRENTFORD, ENGLAND [GSK.COM]	\$30.645	\$4.987	Triumeq	3.535
				Advair	3.234
				Tivicay	2.188
9	Amgen THOUSAND OAKS, CALIFORNIA [AMGEN.COM]	\$22.533	\$3.657	Enbrel	5.014
				Neulasta	4.475
				Prolia	2.291
10	Gilead Sciences FOSTER CITY, CALIFORNIA [GILEAD.COM]	\$21.677	\$3.897	Genvoya	4.624
				Truvada	2.997
				Epclusa	1.966

Source: EvaluatePharma® May 2019, Evaluate Ltd, www.evaluate.com

*numbers USD in billions

How the listings were compiled: 2018 Rx Sales and R&D Spend analyses were provided by life science market intelligence firm Evaluate Ltd via its EvaluatePharma® service, www.evaluate.com. *Pharm Exec* would like to thank EvaluatePharma for assisting in the development of this year's Pharma 50 listing. **PLEASE NOTE:** 2018 figures represent prescription pharmaceutical sales from the named company only, and exclude revenues from royalties, co-promotions, etc., as well as sales from non-prescription pharmaceuticals. Evaluate's Sales and R&D Spend figures represent the fiscal year that ended in 2018. For most American and European companies, that means the year ending December 31, 2018. For many Japanese companies, the fiscal year ending March 31, 2019, was used. Historic averages were used in the conversion of companies' native currency to USD.

Figure 5: Concentration in the healthcare sector means that investors could bring significant changes in lobbying practices with targeted engagement at just 10 companies. Source PharmaExec:

<https://www.pharmexec.com/view/pharm-execs-top-50-companies-2019>

The Healthcare Sector

The healthcare sector is vast and encompasses healthcare services, pharmaceutical drugs, medical equipment, biologics, and veterinary healthcare. Healthcare services are the largest segment of the healthcare market, accounting for around 80% of the total global market in 2018. Within the healthcare services segment, spending on the global geriatric care market - home health, remote patient monitoring, etc. - is expected to exceed US\$1.4 trillion by 2023 as OECD countries age.⁵⁷ Healthcare services are followed by pharmaceutical drugs, medical equipment

⁵⁷ '2020 Global Health Care Outlook Laying a foundation for the future:'

<https://www2.deloitte.com/global/en/pages/life-sciences-and-healthcare/articles/global-health-care-sector-outlook.html>

and other segments in the global market share. Each of the sub-sectors are summarised in turn below and all are major constituents in the investment universe of large global investors.⁵⁸

Healthcare services

The health care delivery industry owns and manages hospitals, clinics, and other related facilities. The industry is primarily engaged in inpatient and outpatient care, anatomical pathology services, and clinical laboratory services and has been heavily involved in the global pandemic response to coronavirus.⁵⁹ A portion of the industry is public and a large segment of the market is controlled by a handful of global companies.⁶⁰ Health care services are increasingly fragmented into specialized facilities providing a range of care including surgery, mental health, hospice, and homes for the elderly. Growth in the G20 healthcare delivery industry is driven by the increased prevalence of disease associated with unhealthy lifestyles and an aging population

Pharmaceuticals

Pharmaceutical distributors, acting as wholesalers, have the power to negotiate with manufacturers, and subsequently play a critical role in pricing and product selection, particularly in the US market. Recent increases in drug prices indicate the extent of market power wielded by larger US companies, Approximately 94% of widely-used brand-name drugs on the market between 2005 and 2017 more than doubled in price during that time, and the average price increase in 2017 was 8.4%, four times the rate of inflation, according to the AARP Public Policy Institute.⁶¹

Recent developments in pharmacogenomics, proteomics, molecular biology, bioinformatics, biomarker-driven studies, systems therapeutics, drug-target interaction prediction and artificial intelligence are all credited with revolutions in drug discovery and development. However, there are signs that excessive pricing of prescription pharmaceuticals, and reliance on a small number of high-profit margin projects is unsustainable.

In the US market, the high price of prescription drugs is a source of ongoing controversy which the largest investors have not yet engaged on. Corporations state that the high costs are the result of pricey research and development programs. Critics point to the development of drugs having only small incremental benefit. Rather than change their practices, Pfizer has made it a priority to fund and to create think tanks around the world to influence the public policy debate in line with

⁵⁸ 'The \$11.9 Trillion Global Healthcare Market:'

<https://www.businesswire.com/news/home/20190625005862/en/11.9-Trillion-Global-Healthcare-Market-Key-Opportunities>; and

<https://www.msci.com/documents/1296102/11185224/GICS+Methodology+2020.pdf/9caadd09-790d-3d60-455b-2a1ed5d1e48c?t=1578405935658>

⁵⁹ <https://www.sasb.org/wp-content/uploads/2019/08/SASB-Health-Care-Delivery-Industry-Brief.pdf>

⁶⁰ 'Why Does a Hospital Monopoly Want to Re-Open the Economy?:'

<https://mattstoller.substack.com/p/why-does-a-hospital-monopoly-want>

⁶¹ 'Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update:' <https://www.aarp.org/content/dam/aarp/ppi/2018/09/trends-in-retail-prices-of-brand-name-prescription-drugs-year-end-update.pdf>

its narrow focus on raising profit margins. This approach to policy capture is effective, with both the RAND Corporation⁶² and authors from the National Bureau of Economic Research⁶³ arguing that price controls stifle innovation and are economically counterproductive in the long term.

Medical equipment

The medical equipment & supplies industry researches, develops, and produces medical, surgical, dental, ophthalmic, and veterinary instruments and devices. Products are used in hospitals, clinics, and laboratories, and range from disposable items to highly specialized, large scale equipment.⁶⁴ The increased prevalence of diseases associated with unhealthy lifestyles and an aging population are important factors expected to boost growth in this industry through the 2020s.

In the United States, in recent years, a top priority for the field has been making sure the cost of medical devices is covered under the Affordable Care Act, passed in 2009. In addition, it has fought a tax on these devices that is part of that law. The tax, which was meant to help offset costs of the bill more broadly, was implemented in 2013. But fierce industry lobbying led Congress to declare a two-year moratorium on collecting those levies in 2016 and 2017.⁶⁵

Biotech & life sciences

Biotechnology companies develop products to treat new medical needs through the technological application of molecular and cellular systems. The industry is driven by research and development and is characterized by a high risk of product failure. Biotechnology firms are dependent on a skilled workforce and are closely regulated, and rely, like other parts of the industry, on a revolving door with national regulators.⁶⁶

Veterinary healthcare

The unnecessary use of antibiotics in human medicine and agriculture, particularly their use to make animals grow faster rather than treat disease, are major contributors to growing levels of resistant bacteria. As a result of growing overuse of antibiotics in livestock raising, the WHO considers antibiotic resistance one of the greatest threats to public health.⁶⁷

⁶² 'Pharmaceutical Pricing The Use of External Reference Pricing:' <https://www.rand.org/pubs/periodicals/health-quarterly/issues/v3/n2/06.html>

⁶³ NBER (2020) 'The Effect of Price Controls on Pharmaceutical Research:' <https://www.nber.org/digest/may05/w11114.html>

⁶⁴ SASB (2018) 'Medical equipment & supplies:' https://www.sasb.org/wp-content/uploads/2018/11/Medical_Equipment_Supplies_Standard_2018.pdf

⁶⁵ 'Medical Supplies: Background:' <https://www.opensecrets.org/industries/background.php?cycle=2020&ind=H4100>

⁶⁶ 'Biotech lobbying group selects doctor, J&J exec as next chief' (14.05.2020): <https://www.spglobal.com/marketintelligence/en/news-insights/latest-news-headlines/biotech-lobbying-group-selects-doctor-j-j-exec-as-next-chief-58632145>; Prasad et al. 'Future jobs of FDA's hematology-oncology reviewers:' <https://www.bmj.com/content/354/bmj.i5055>

⁶⁷ WHO 'Antibiotic resistance:' <https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance>

The global animal medicine and healthcare products market is highly concentrated and is expected to hit US\$172 billion by 2025.⁶⁸ The top ten companies in the global animal medicine sector were responsible for almost 70% of the total market transaction volume in 2018, including Zoetis, Boehringer Ingelheim, Merck & Co., Elanco Animal Health, and Bayer AG. The animal medicine market is segmented by type of medicine into veterinary pharmaceuticals and feed additives. The veterinary pharmaceuticals market was the largest segment of the animal medicine market. More than 73% of all antimicrobials sold in the world are used in animals.⁶⁹ Antibiotics is an important profit centre with pharmaceutical companies earning about \$5bn a year from the production of antibiotics for farm animals. The European animal antibiotics market is worth about \$1.25 billion a year, and the US animal antibiotics industry about \$2 billion a year.⁷⁰ With the global antibiotics market worth about \$45bn, animal antibiotics represents a small but stable revenue source for the big pharmaceutical companies.

The feed additives market is further segmented by type of additive into medical feed additives and nutritional feed additives. The medical feed additives market was the largest segment of the feed additives market, accounting for \$2.6 billion or 61.5% of the total in 2019.

⁶⁸ <https://www.gminsights.com/industry-analysis/animal-healthcare-market?>

⁶⁹ Van Boeckel et al (2017) 'Reducing antimicrobial use in food animals:'
<https://science.sciencemag.org/content/357/6358/1350>

⁷⁰ 'How much does big pharma make from animal antibiotics?' (19.06.2018):
<https://www.theguardian.com/environment/2018/jun/19/how-much-does-big-pharma-make-from-animal-antibiotics>

Antibiotics Sold in the U.S.

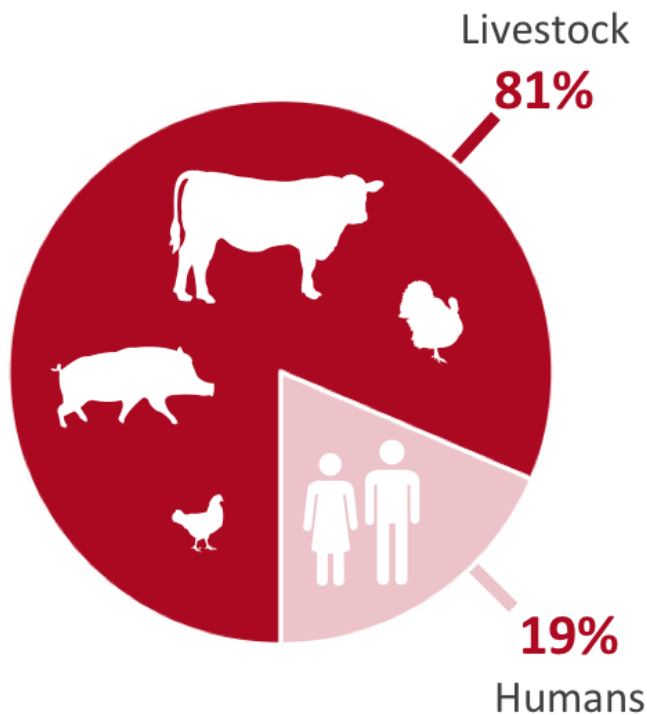


Figure 6: heavy antibiotics use in livestock in the United States and Canada, as well as other jurisdictions, increases risk of antimicrobial resistance to these medicines. Source: FDA (2016)⁷¹

The ability of animal healthcare companies - who include the world's largest drug manufacturers - to continue to sell antibiotics for livestock in unregulated markets like India and China should prompt further enquiry from investors.

Background on healthcare sector investing

Healthcare is one of the largest sectors in the world and it is growing. The global healthcare market was worth around \$9 trillion in 2018. The sector is expected to continue growing at an estimated CAGR of 8.9% to nearly \$11 trillion by 2022.⁷² Going forward, faster economic growth, technological developments in biotech and the increasing prevalence of "lifestyle diseases"⁷³ are expected to drive the growth in the sector. This means that there is an opportunity for investors

⁷¹ <https://www.fda.gov/media/102160/download>

⁷² 'The \$11.9 Trillion Global Healthcare Market' (25.06.2019): <https://www.businesswire.com/news/home/20190625005862/en/11.9-Trillion-Global-Healthcare-Market-Key-Opportunities>

⁷³ WHO (2018) 'Noncommunicable diseases: key facts:' <https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases>

to engage with growing global companies to embed respect for public policy into their operating models. Coronavirus is likely to accelerate this growth trend as governments come under political pressure to invest in public health. This growth means that the world's largest investors will expand their investment in the sector, across public and private markets⁷⁴ and lobbying is poised to continue to play a key role in the business model for industries in the sector.

⁷⁴ 'Asia-Pacific: Healthcare Private Equity Is on a Multiyear Growth Trajectory' (08.04.2020): <https://www.bain.com/insights/asia-pacific-global-healthcare-private-equity-and-corporate-ma-report-2020/>; 'Investment: Healthcare looking strong amid demand for alternative property' (12.04.2020): <https://www.knightfrank.co.uk/research/article/2020-03-12-investment-healthcare-looking-strong-amid-demand-for-alternative-property>

Top 25 US companies and trade associations by lobbying spend⁷⁵

Company or trade association	Amount (USD\$)
Pharmaceutical Research & Manufacturers of America	29301000
Biotechnology Innovation Organization	12210000
Pfizer Inc	11000000
Amgen Inc	10940000
Roche Holdings	10235000
Bayer AG	9140000
Bristol-Myers Squibb	7230000
Eli Lilly & Co	7060000
Merck & Co	6955000
AbbVie Inc	6340000
Novartis AG	6130000
Johnson & Johnson	5830000
Gilead Sciences	5720000
Sanofi	5117000
Medtronic Inc	4879000
Association for Accessible Medicines	4750000
GlaxoSmithKline	4690000
Pharmaceutical Care Management Assn	4248140
Horizon Therapeutics	4130000
Mylan Inc	4060000
Abbott Laboratories	3970000
AdvaMed	3880000
Alkermes Plc	3730000
Allergan plc	3070000
AstraZeneca PLC	2880000

⁷⁵ 2019 figures from: <https://www.opensecrets.org/federal-lobbying/industries/summary?cycle=2019&id=H04>

Appendix - Healthcare sector lobbying organisations

America's Health Insurance Plans

The American Hospital Association

American Medical Association

Animalhealth Europe

Health for Animals

European Federation of Pharmaceutical Industries and Associations (EFPIA)

American Orthotic & Prosthetic Association

Health Industry Distributors Association

Medical Device Competitiveness Coalition

Medical Device Manufacturers Association

The International Life Sciences Institute

About Preventable Surprises

Preventable Surprises is a 'think-do' tank focused on systemic ESG risks in the financial system. We work with a group of positive mavericks within the investment industry to persuade key stakeholders in the financial sector to better address systemic risks.

Regulators, the media, NGOs and consumers all have a role to play in building a more transparent and sustainable market system, yet much of the power lies with corporations and their investors. Our work focuses on institutional investors because, through the trillions of dollars in assets under their management and their influence over all sectors of the economy, they have enabled corporate and market dysfunction. This dysfunction contributes to the build-up of systemic risks like climate change, economic inequality and social discord. Long-term investors cannot use stock-picking or hedging strategies to avoid systemic risk. For example, in the case of climate change, institutional investors' end beneficiaries will pay the price as the extent of portfolio risk is revealed on their retirement savings and on their quality of life. That is why investors must mitigate systemic risk through [forceful stewardship](#).

About the Corporate Lobbying Alignment Project (CLAP)

The CLAP is an applied research and engagement project launched in June 2020 working to make corporate political capture a central component of investors' approach to ESG stewardship and integration in the 2021 proxy season and beyond. It will leverage information on the state of play for key sectors and share lessons learned from past investor engagements. Through research interviews and a series of events, the programme will engage the global investment community to help prioritise and inform areas for action.

If you are an investor or other stakeholder in the institutional investment or policy system with a story about corporate lobbying that undermines healthcare, climate action, human rights, and other important public policy aims, we want to hear from you. We will not share your name or any identifying information without your express permission. **Get in touch today:** research@preventablesurprises.com