



# EUROHEALTH

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## Commercial Determinants of Cancer Control Policy



### ➤ Commercial Determinants of Cancer Control Policy

- Understanding the commercial determinants and tackling this challenge
- Countering corporate tactics for better cancer prevention
- The commercial drivers of screening
- Considering non-pharmaceutical technologies
- Commercial determinants of cancer medicines
- Commercial and social determinants in palliative care
- The role of governments and international agencies
- Ethical questions: Policies that promote equity, autonomy, and wellbeing

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## Commercial Determinants of Cancer Control Policy Special Issue

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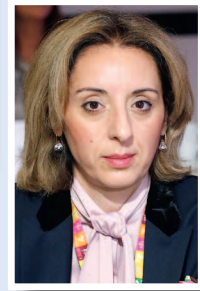
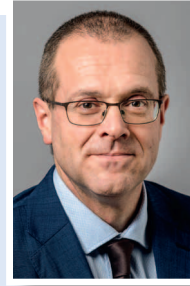
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# FOREWORD

## Commercial Determinants of Cancer Control Policy



With the increasing burden of cancer on populations, health systems and the consequent tremendous impact on societies, there is a moral, economic and social imperative to step up efforts to reduce cancer incidence and mortality. Broadening the discussion on cancer policy is urgent because almost everyone can be affected by cancer in their lifetime, either directly or indirectly through their loved ones. Moreover, understanding the broader determinants is crucial for governments so that they can provide the most effective (and cost-effective) interventions.

Despite well-established evidence on the link between cancer and certain risk factors such as tobacco, alcohol, processed meat etc., gaps remain regarding the way in which the commercial interests of these and other industries influence the burden of cancer on population health. Thus, it is necessary to analyse the commercial determinants and understand their influence, both positive and negative, as a complex set of power dynamics and interests at various levels – from influence at a national level, to the global influence of transnational corporations.

The interplay between cancer and its commercial determinants is complex and constitutes a continuum. The tobacco industry, on the one hand, derives its profits from the sale of a carcinogenic products. In the case of such commercial determinants, the focus of public health policy should be to directly counter their interests and influence. Other sectors, such as the medical technology and pharmaceutical industries, contribute to innovations that improve the outcomes of cancer. Given the size and lucrative nature of the cancer market, these industries will have more nuanced influences on research, development, pricing, and marketing of technologies and medications. In such cases, the public sector should engage in ways that optimises public interests and value to society.

Commercial determinants can also have links with other health determinants, all of which can contribute to the widening of health inequalities. Transparency in these relationships and how they adapt to changes in the policy-making landscape can help ensure that

partnerships with the private sector lead to population health gains. Because healthier populations lead to more dynamic and thriving economies, multiple disciplines and perspectives should be part of this discussion, including decision makers, patients, health professionals, professional societies and corporations as well as economists, philosophers and lawyers.

Simultaneously, good governance at different levels is necessary. The precedent established by the WHO's Framework Convention on Tobacco Control shows that strong leadership, combined with committed stakeholders and public awareness, can lead to breakthroughs in public health policy. This is also possible through collaboration with different levels of policymaking in national governments and international organizations, such as the European Commission, to create a legal and political landscape that can lead to improving population health.

This issue of Eurohealth offers a first step towards a deeper understanding of the role that negative commercial determinants may play in cancer policy. The articles discuss the full cancer continuum from prevention, early detection, diagnosis, treatment, medicines and palliative care, and go on to examine related philosophical and behavioural insights and the role of governments and international agencies. Examples of possible actions at policy-level are provided, which can be used to optimise the interaction with the private sector and confront future challenges.

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FOREWORD

# THE DARK SIDE OF THE COMMERCIAL DETERMINANTS OF CANCER POLICY: THE NEED TO UNDERSTAND IT AND TO FIND ALTERNATIVES TO TACKLE THIS CHALLENGE

By: Jose M Martin-Moreno, Tit Albreht, Monika Kosinska and Marilys Corbex

**Summary:** Cancer is a major health, social and public policy challenge. As such it touches upon most relevant functions and domains in a modern society. If we want to successfully tackle it, it is crucial to understand the interplay of political, environmental, social, and commercial determinants. The latter are those private-sector activities that affect the health of populations and, in this issue, we specifically focus on their potential dark side, where commercial interests take precedence over nobler health goals. We seek answers to understand their dimensions and how to govern them along cancer's continuum, from prevention and screening, through integrated treatment and palliative care, to provide a potentially useful descriptive and analytical basis for governments and the international community.

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## Cancer as a global health priority

Cancer is a leading cause of global illness. Some 4.8 million new cases were diagnosed in 2020 in the World Health Organization (WHO) European Region, and it remains an important scientific, health care and practice challenge as well as a challenge for public policy. As many as 2.7 million people in the European Union (EU) were diagnosed with cancer in 2020<sup>1</sup> and this burden of disease is going to further increase due

to population growth and ageing.<sup>2</sup> This enormous and largely preventable human and social cost is further impacted by the COVID-19 pandemic, not least because of reported interruptions or delays in primary and secondary prevention programmes (screening), delays in diagnosis, and the organisational impact on the care provided by comprehensive secondary and tertiary oncology services.<sup>3</sup> In addition to these facts and trends, there are adverse developments with an increasing share of

overweight and obese population in the region, made worse by the reduction in physical activity and restrictions imposed by COVID-19 lockdowns.<sup>4</sup>

Cancer control as defined by WHO and also often referred to as “cancer prevention and care” consists in a continuum from prevention, early detection (i.e. screening and early/rapid diagnosis of symptomatic patients), diagnosis and treatment, to palliative/supportive care and survivorship. Evidence-based policies and guidance have been articulated by WHO along each dimension of this continuum that enable countries to better control cancer and better support cancer patients in a cost-effective way.<sup>5</sup> The vision and intention are clear. As a society, cancer policies must ensure a context and process that underpins sound cancer prevention strategies,<sup>6</sup> and that supports patients and their families in achieving the best possible diagnosis and treatment and the best possible life in the face of cancer.<sup>7</sup> But this vision is impossible to achieve if we do not address the underpinning social, economic and commercial considerations along the cancer continuum. Cancer’s complexity and scale means that political, social, environmental, and commercial determinants (see Box 1) play influential roles and must be addressed in order to develop implement effective policy solutions.<sup>8–10</sup>

## Understanding the full spectrum of commercial determinants

### Why focus on commercial determinants of cancer policy?

This special issue of Eurohealth was conceived following the initiative of the cancer control team of the WHO Regional Office for Europe. WHO European data and missions in countries show that while much is known about efficient and cost-effective policies to prevent, better diagnose, treat and control cancer, these

### Box 1: A definition of the commercial determinants of health

As the field of enquiry in social determinants of health has moved further ‘upstream’ in recent years, we have seen a greater awareness and understanding of the importance of commercial determinants of health as a subset of the social determinants. A definition on “the commercial determinants of health” was presented to the United Nations (UN) General Assembly 2017: “*The commercial determinants of health are those conditions, actions and omissions that affect health. Commercial determinants arise in the context of the provision of goods or services for payment and include commercial activities, as well as the environment in which commerce takes place. Commercial determinants can have beneficial and/or detrimental impacts on health.*”<sup>12</sup> Or as proposed more recently by Maani et al., “*Commercial determinants of health are, broadly speaking, those activities of the private sector that affect the health of populations.*”<sup>13</sup> See also Maani et al. (2021)<sup>14</sup> and Mialon (2020).<sup>15</sup>

policies remain insufficiently applied, with one of the key barriers being commercial determinants. Furthermore, the WHO Conference on Screening, held on 11–12 February 2020 in Copenhagen Denmark, highlighted the role of commercial drivers as a critical issue for consideration for policymakers, with implications for patients, professionals, and civil society.

Despite the relatively new field of commercial determinants in the literature, there are emerging themes which are very important for cancer policy and the cancer control continuum, and which are addressed throughout the articles in this issue.

### Social and commercial determinants in cancer control

The political and social context for public health has evolved over the last two decades in many ways: new challenges; redistributions of power and resources notably toward commercial entities, environmental and demographic pressures; as well as changes in social and behavioural norms. We know that cancer rates are increasing, and that relative survival tends to be lower for patients living in disadvantaged communities. The so-called social determinants of health are important for understanding the distribution of the cancer burden and the chances of survival (see also definitions below). These include access to housing and housing conditions, the level of exposure to environmental risks, health

literacy, educational level and employment opportunities, as well as access to quality health care, and social support and financial protection when off work or needing to access care.<sup>11</sup>

In general, however, as the UN / WHO definition outlines, private sector activities are neither intrinsically helpful nor harmful to health and in many cases, they fulfil an essential function in society and often provide essential goods and services adapted to public needs. The focus of this issue is the *dark side* of commercial determinants of cancer, which has not yet been thoroughly explored. This dark side is where commercial forces exert power and influence to privilege commercial for-profit interest over human, social and environmental associated costs. In the context of cancer, this means the undermining of the goal of preventing cancer, and of providing better care and support for people suffering from cancer, and where necessary ensuring patients’ dignity and the ability to live as well as possible at the end of life.<sup>16</sup> It is necessary to stress that the main objective of cancer care should focus on the outcomes, in particular patient-relevant outcomes, and on the quality of life rather than solely on clinical process, even if these appear to meet the required and agreed performance criteria. While these are often met at the expense of patients, they frequently fall short of a clearly expressed patient preference.

Given the complex relationships of stakeholder interests and influence, it is

critical to take a power and governance lens in order to understand the commercial determinants of cancer. This involves understanding the drivers, the challenges of private sector involvement and agenda-setting, and the associated human, social and economic costs of failing to consider the commercial determinants of cancer.

### Understanding the impact of commercial actors on cancer control

Firstly, we need to understand the impact of commercial actors across the cancer continuum. This includes, as highlighted by Galea and Castro in this issue, tobacco, alcohol, and the underpinning corporate tactics to undermine public health objectives and actions to prevent non-communicable diseases, including cancer.

One significant corporate strategy highlighted by the authors is marketing. As Hogarth shows us in his article, this includes the recent direct marketing to consumers of screening tests and explain that this sensitises public policymakers to a form of cultural capture. Kaasa et al. in their article argue that marketing of pharmaceuticals distracts from patient-centred social models, especially at the end of life.

Regarding pharmaceuticals, Booth et al. highlight how the private sector now determines nearly the entire cancer biopharmaceutical ecosystem across Europe. Similarly for non-pharmaceutical technologies, Sullivan et al. warn of the commercial drive both in terms of new technologies as well as the challenges to health systems and outcomes through outsourcing to the private sector.

Finally, Kaasa et al. demonstrate that although the integration of patient-centred care and tumour-centred care is needed during the end of life, commercial barriers play a key role in hindering this integration, giving clear preference to the latter.

### Effective governance of commercial determinants of cancer across the continuum

Fundamentally, the challenge that we face is how to govern the commercial determinants of cancer across its

control continuum. Plutynski presents a set of policy options ranging from regulatory tools to improvement in medical education, but with a focus on transparency amongst all stakeholders. These are also echoed by Borisch and Yared, who further explore what can be done by public administrations, national governments, international agencies and civil society in trying to mitigate the harms associated with conflicts of interest.

Booth et al. highlight that in medicines, there is a clear need for high standards, both at European Medicines Agency level and through stronger health technology assessment mechanisms coupled with more sophisticated pricing and reimbursement systems at national level. However, they argue it is the cultural change required in clinical/medical oncology that is central. They call for a new contract with private sector interests for cancer medicines, which includes the major federal and philanthropic research funders.

### Evidence base for better policy development and action

Good governance should be evidence informed, and in addressing the commercial determinants of cancer it is critical that we take an evidence-based approach. Hogarth demonstrates this through his critique of the commercial pressures on policymakers to adopt new screening initiatives.

Plutynski approaches this through the influence of commercial determinants on behavioural and cultural practice in the context of cancer policy. Kaasa et al. raise the issues of insufficient quality of research and regulatory standards, and the critical absence of correlation between economic incentives and what is truly sought in terms of overall patient quality of life.

### Innovation as a panacea

It is striking that most of articles in this issue raise the concern that blind faith in innovation is deceiving. We know that innovation has great appeal to policymakers, clinicians, the public and donors, all the more since it is assumed to boost economies. It is taken for granted

that innovations are good for saving lives with priority given to short-term outcomes and processes. However, Hogarth, Booth et al., Sullivan et al., and Kaasa et al., all warn against embarking on new preventive, diagnostic or therapeutic innovations without a rigorous assessment of their safety and actual benefit for the population and an adequate evidence base to demonstrate their effectiveness and cost-effectiveness.

### Civil society, professional associations and patient voice

As in many areas of public health, the governance of the commercial determinants of cancer requires multi-sectoral and multi-stakeholder considerations. Borisch and Yared remind us of the challenges of multi-sectoral partnerships, and Hogarth as well as Borisch and Yared highlight the role of companies who use patient and cancer control organisations to boost sales. As an illustration, Booth et al. provide us with an example of patient advocacy for new cancer medicines. Hogarth highlights that physicians, scientific societies, health care and patient organisations, insurance bodies and policymakers may all be exposed to commercial drivers. These articles call for better informed patient groups and professionals to ensure that patients' needs remain the ultimate goal.

Kaasa et al. further emphasise the need to strengthen the voice of patients, particularly in palliative care, and highlight that the commercial determinants reinforce the stigma around palliative care promoting a tumour-centred focus of cancer care. They call for a healthier collaboration between the pharmaceutical industry and health professionals.

Plutynski reminds us that policies across the cancer continuum need to engage all relevant stakeholders if we are to improve overall population health and wellbeing.

### Aim and structure of this special issue

The aim of this special issue is to make readers better aware of the importance of commercial determinants in cancer policymaking, how they shape cancer prevention and care, and what are the

possible avenues to deal with them efficiently. It explores the commercial determinants across the cancer continuum, from prevention (see article by Galea and Castro), through screening (article by Hogarth), diagnosis and treatment (article by Sullivan et al.), cancer medicines (article by Booth et al.) and end-of-life care (article by Kaasa et al.). It also explores elements of the philosophical and ethical dimensions (in the article by Plutynski) and proposes options to governments and the international community to better address commercial determinants (article by Borisch and Yared).

The challenge presented is not small and perhaps best highlighted by Booth et al. in their article on cancer medicines. They remind us of the rapid growth in pharmaceutical revenues generated by the sales of cancer medicines despite a lack of return in terms of survival or cure during the same period. Furthermore, Kaasa et al. note that while it is easy to sell the message “we will cure cancer”, the reality is that we need to critically rethink how to approach cancer across the continuum to ensure that patient-centredness and end-point outcomes (and not commercial interests) are central in our practices, our strategies and our policy decisions.

## Conclusion

In summary, there are matters of ethics and justice across the board, as illustrated in the articles of this special issue. These issues have to do with respect for autonomy, equity, and beneficence. Autonomy, with strong support and transparent communication. Equity in relation to risk identification and prevention resources, early detection and screening tools, diagnostic and therapeutic alternatives, and proper palliative care whenever it is needed. To ensure beneficence, governments must resist commercial influence on regulatory standards and health policies that may or not promote overall wellbeing. Genuine interest on the part of governments should materialise in terms of increased public support and funding for research, the development of truly necessary innovative medicines, the evaluation of all health technologies for informed choice and quality assurance for the good of citizens in general and patients in particular.

This special issue marks a first review of the commercial determinants of cancer across its continuum. Many areas remain to be explored: the commercial dimensions of both environmental and social determinants of cancer; the key role played by civil society and patient groups in dealing the commercial determinants of cancer; the need for proper corporate accountability through investor or board mechanisms; and the implications for local government and community actors just to name some issues that warrant further inquiry. What is clear is that more attention to the commercial determinants is needed by the cancer prevention and care community, researchers, clinicians and public health professionals, civil society and patient groups alike. Furthering our understanding in this area and other complex drivers of cancer policies will be a key step to better control cancer in the WHO European Region and its ‘United Action Against Cancer’ as well as meeting the ambitions and successfully implementing ‘Europe’s Beating Cancer Plan’. The commercial determinants of cancer remind us that whole-of-government but also whole-of-society approaches are critical to address the challenge we face as a society, and that fundamentally, health remains a political choice.

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# COUNTERING CORPORATE TACTICS FOR **BETTER CANCER PREVENTION**

By: **Gauden Galea** and **Lea Castro**

**Summary:** A range of behavioural and environmental factors lead to an increased incidence of cancer. Many of these are preventable, but corporate interests and actions have contributed to undermining public health efforts to tackle them. Examples of tactics include fear mongering about regulation, burnishing reputations with funds as corporate social responsibility, recruiting front groups, denying the impact of their products or deflecting attention from their harms, and attempting to shape the evidence base and divide the public health community. It is therefore crucial for practitioners and decision-makers to strengthen their own awareness of the typical tactics in the corporate playbook and plan for effective responses.

**Keywords:** *Neoplasms Prevention and Control, Alcohol Industry, Tobacco Industry, Corporate Policy Influence, Public Policy*

## Introduction

According to the World Health Organization (WHO), 30–50% of all cancer cases are preventable, with tobacco use the main preventable cause of cancer in Europe. Other major risk factors are alcohol consumption, overweight and obesity, a poor diet and insufficient physical activity. Exposure to the sun, to sources of radiation, and to other chemical carcinogens including from the beauty industry also increase the risk of developing various forms of cancer.

The increased use of many of these products is related to the commercial determinants of cancer, which share the three characteristics of:

1. a clear causal link with cancer;
2. a defined commercial interest as the main driver of their production and sale;
3. a transnational ecosystem of producers, retailers, marketers, politicians, banks, trade associations, think tanks, some scientists, and other entities devoted to the sale of these commodities, fitting the definition of what has been called the “corporate consumption complex”.<sup>1</sup>

Although similar tactics are also used in other industries affecting cancer prevention, including the pharmaceutical, chemical and food industries, it is beyond the scope of this article to review the entire landscape of risk and industries. Rather this paper will focus on tobacco and alcohol, for the following reasons:

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*The authors alone are responsible for the views expressed in this article, and they do not necessarily represent the decisions or the stated policy of their organisations.*

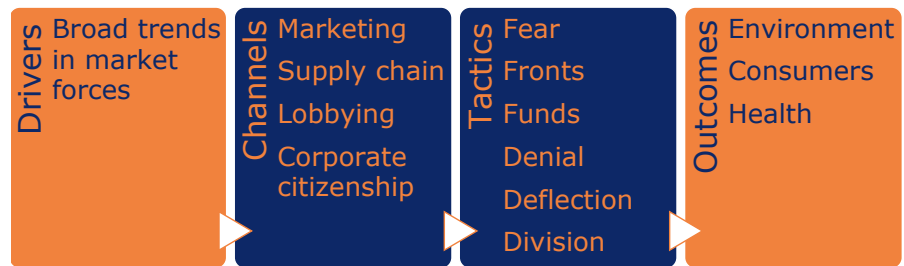
- They are both legally sold addictive substances which have been proven Group 1 carcinogens, notably by the International Agency for Research on Cancer. They cause a significant proportion of cancer, and a lot of experience has been accumulated about their control;
- There are similarities in the playbook of the industries behind them, both acting to create policy environments that favour their trade, and averting the attention of policymakers and the population from their harms or from effective action to control their consumption;
- Studying their tactics provides some insight on the behaviour of other industries;
- In the context of the COVID-19 pandemic, both industries are behaving in ways that attempt to rehabilitate their image or make them appear as allies in the global efforts to control the pandemic.

“Tactics in the corporate playbook include fear, funds, fronts, denialism, deflection, and division”

### The Core Determinants of cancer

Tobacco and alcohol each independently increase the risk of cancer at any level of consumption. Europe is one of the largest markets for alcohol sales and is the region with the highest proportion of disease and premature mortality due to alcohol. According to Eurostat, in 2019 households in the EU spent 4% of total expenditure on alcohol beverages and tobacco products.<sup>2</sup> In Europe, approximately 20% of the adult population are tobacco users and one in five people aged 15 years and older report heavy drinking at least once a week in the

**Figure 1: Channels and Tactics: Points of Intervention on the Commercial Determinants of Cancer Risk**



Source: Adapted and expanded from a model in Kickbusch et al.<sup>4</sup>

European Union. The European Region has the highest average of current tobacco use among adolescents.<sup>3</sup>

Actions by tobacco and alcohol industries may thus be regarded as a core set of commercial determinants of cancer. The evidence for their causal link with cancer is incontrovertible. This independent and synergistic carcinogenicity of these two substances, combined with the high burden of cancer attributable to them, and the availability of highly cost-effective interventions, make tobacco and alcohol control the litmus test for the credibility of any programme that purports to prevent cancer.

### The Core Tactics

The classic definition of commercial determinants of health examines the drivers, channels, and outcomes of corporate power and influence, summarised in **Figure 1**. In defining points of intervention, public health practitioners have relatively little influence on the drivers, which tend to be market forces that often transcend national boundaries. Nor can they directly transform the outcomes, beyond using them as performance markers and indicators for monitoring, evaluation, and the subsequent proposal of corrective actions.

From the practitioners' point of view, the points of intervention on commercial determinants of cancer include limiting or blocking the channels of power for corporations and countering the tactics that are typical of their playbook.

Public health action on the recommended policy actions that WHO has named “best buys”<sup>5</sup> due to their cost-effectiveness (i.e. price, availability, and marketing), must include counter-tactics to the corporate playbook. Corporate interests will use their channels and tactics to resist these changes. The public health response needs to find ways to limit the use of the main channels of corporate influence if the ultimate policy goals are to be achieved, including:

- adopting comprehensive bans on advertisement, promotion and sponsorship,
- regulating lobbying,
- controlling supply chains, and
- setting boundaries on the exercise of corporate citizenship.

This article adds to the classical model and further suggests a focus on the main tactics in the corporate playbook as a foundation for planning counter-responses. Multiple sources were used in compiling this list, most prominently, the Tobacco Playbook,<sup>6</sup> [TobaccoTactics.org](http://TobaccoTactics.org),<sup>7</sup> and a systematic review of the alcohol industry response to marketing regulation.<sup>8</sup> Tactics in the corporate playbook include **fear, funds, fronts, denialism, deflection, and division** (see **Table 1**).

### Corporate Tactics in the COVID-19 Era

The pandemic has stressed the corporate sector in several ways and provided them with both opportunities and threats. It is useful to examine how the tactics of

**Table 1:** The six main tactics in the corporate playbook

Tactic	Methods
<b>Fear</b>	Fear mongering by industry takes diverse forms. It includes lawsuits or threats of lawsuits on the grounds of infringing industry's commercial rights including in intellectual property and economic freedom. It also includes generating fear that constraining the industry would have a disproportionate impact on the economy and on employment.
<b>Funds</b>	Industry funds are used to win over support to protect corporate interests from interference. These include direct support to political campaigns and politicians, corporate social responsibility efforts to whitewash or "greenwash" * their credentials, and, where allowed, using sponsorship and marketing budgets to gain allies in the media, sport, and cultural scenes.
<b>Fronts</b>	Corporate power is exerted through front groups that claim to represent the interests of the public or of other industrial sectors. Curbs on public smoking or imposition of licensing hours, for instance, are often initially opposed by the tourism and hospitality industries as being detrimental to their viability, even though these industries are usually found to benefit commercially when the laws are enacted and enforced. Corporate interests also use front groups (such as "smoker's rights" groups) to undermine the confidence of policymakers by belittling or denying the support of the public for effective public health measures.
<b>Denialism</b>	It is a reflexive action of the corporate sector to deny the link between its products and health effects, by impugning the findings of health research or the researchers involved. Denialism was a strong feature of the tobacco industry response to the initial findings linking tobacco and cancer and has since become an established part of the playbook for other industries. This systematic deployment of doubt with the support of corporate interests has also, at times, acquired an ideological and political motive. <sup>9</sup>
<b>Deflection</b>	Industries deflect attention on them and their products using several tactics. They claim health benefits (e.g., "the benefits of red wine"). They fund alternative research directly or through foundations, such as the Foundation for a Smoke Free World to create confusion. They also deflect liability by running campaigns focused on individual responsibility, blaming the consumers rather than the industry itself, for instance, in the ubiquitous "drink responsibly" campaigns. Faced with the prospect of regulation, industry reverts to the trope that voluntary agreements, self-regulation, partial bans, or even public-private partnership are more democratic or market-friendly.
<b>Division</b>	While the resolution of alternate hypotheses is inherent to the scientific method, corporate tactics have used it to delay effective action on curbing consumption of their products. The claims of protective effects of alcohol under certain conditions creates a language divide, constraining public health work to addressing the "harmful use of alcohol", implying there is a beneficial use and obfuscating the fact that any level of alcohol consumption is carcinogenic. <sup>10</sup>

Source: Authors' own.

Note: \*The Cambridge Dictionary defines *whitewash* as "an attempt to stop people finding out the true facts about a situation" and *greenwash* as "behaviour or activities that make people believe that a company is doing more to protect the environment than it really is".

both industries have adapted to these challenges. The tobacco and alcohol industries have both capitalised on the pandemic.<sup>11 12 13</sup>

The tobacco industry has used its resources to strengthen their channels of influence as well as to double down on tactics that have stood the test of time for them. They increased their access to senior policymakers through large donations to countries since the early months of the pandemic, especially so in countries home to large numbers of smokers.<sup>14</sup> They deflected attention from the harm of tobacco by supporting access to personal protective equipment for health care workers. Economic stresses provided opportunities for industry lobbyists to work to delay introducing or implementing tobacco control measures.<sup>15</sup> Notably, while it is more feasible for high-income countries to reject donations from

the industry to contain the COVID-19 pandemic, it is less so for low- and middle-income countries. Such donations help strengthen the relationships between governments and the industry and they are used as leverage. For example, during lockdowns, the tobacco industry has been successful at lobbying to keep their products on essential goods rosters and to continue cigarette production despite a ban on non-essential manufacturing.<sup>16</sup>

During lockdowns in the United Kingdom and Australia, alcohol brands intensified their social media advertising and adapted their messaging, deflecting from the dangers of consumption, and exploiting the zeitgeist ("We're in this together") to encourage stockpiling of alcohol and virtual drinking events among friends. Donations towards pandemic prevention efforts allowed brands to further distract

attention from the harm of their products, and provided a "COVID-washing" opportunity, allowing the industry to claim itself a partner in national efforts to control the transmission of infection while at the same time promoting consumption of their products. Nowhere is this more evident than in campaigns that provided alcoholic drinks as an incentive for getting vaccinated.

### Addressing the Commercial Determinants of Cancer Risk

This article has provided a brief survey of two core determinants of cancer risk, extracting lessons on corporate tactics, and expanding on the classical model of commercial determinants from the perspective of health advocates and policymakers. Similar channels of influence and tactics are used by other industries with products potentially

contributing to the cancer burden: the food industry, the beauty and tanning industries, radon and asbestos in the construction industry, and producers of potentially carcinogenic chemicals used in households and occupational settings.

## Public health action must include counter-tactics to the corporate playbook

It needs to be emphasised that the control of tobacco and alcohol requires effective control of price, availability, and marketing, among other “best buys”. This should be the fundamental strategy for public health policymakers. To achieve these strategic aims, public health advocates need to adopt effective counter-tactics to those employed by industry:

1. limiting the channels of influence (marketing, lobbying, licit and illicit supply chains, and the rights and responsibilities of corporate entities) and
2. pre-empting, responding to and regulating the tactics used by companies to resist public health “best buys”.

The Guidelines for implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control (FCTC) provide specific recommendations for addressing tobacco industry interference in public health policies\*. These include establishing measures to limit interactions with the tobacco industry and ensuring the transparency of those interactions that occur, as well as rejecting partnerships and non-binding or non-enforceable agreements with the tobacco industry.

Industry will often claim to be part of the solution and not just part of the problem, proposing nebulous “win-win”

\* The Guidelines are available at: [https://www.who.int/fctc/guidelines/article\\_5\\_3.pdf](https://www.who.int/fctc/guidelines/article_5_3.pdf)

solutions that never truly work. Before politicians are lured into spurious partnerships, they need to consider their legal obligations under the FCTC, and the European Directives and the conflicts of interest involved.<sup>14 15</sup> This extends to other industries such as the “Big Food” transnational companies, not just to tobacco and alcohol.<sup>16</sup>

In the pandemic era and beyond, the influence of these commercial determinants is likely to grow, as governments may find themselves in need of financial support during economic setbacks or become more reluctant to apply measures to control price, marketing, or availability of carcinogenic products such as tobacco and alcohol. It behoves public health advocates to make better use of the provisions of international agreements, such as the WHO FCTC or the WHO Global Strategy to Reduce the Harmful Use of Alcohol to limit the influence of the corporate sector as well as the evidence and guidance of decades of experience in the core determinants of cancer to hem in harmful tactics.

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# THE COMMERCIAL DRIVERS OF CANCER SCREENING

By: Stuart Hogarth

**Summary:** In 1968 Wilson and Jungner established a new framework for the evaluation of screening as a public health intervention and enshrined the ideal of screening delivered as an organised programme. There has been a consequent growth in national bodies dedicated to screening governance but efforts to ensure a more evidence-based approach to screening are threatened by the growing power of corporate actors in a new wave of technological innovation in screening.

**Keywords:** *Screening, Early Detection, Cancer, Commercial Drivers, Commercial Determinants*

## Introduction

Screening a healthy population to detect cancer at an early stage has much appeal to clinicians, the public and policymakers alike. It is assumed that screening is a good thing that can save lives. However, since the publication of seminal work in 1968 by Wilson and Jungner, public health professionals have cautioned against embarking on new screening initiatives (including cancer screening) without rigorous evaluation of the harms and benefits for a population and an adequate evidence-base that demonstrates its efficacy and cost-effectiveness. Following Wilson and Jungner, a growing number of countries now deliver screening as organised programmes, with systems of quality assurance.<sup>1</sup>

Contrary to widely-held beliefs, picking up cancers before they present symptomatically through screening does not necessarily lead to better outcomes at either the individual or population level. In addition, there is now a greater awareness of harms associated with exposing a healthy population to

screening, in particular the problems of overdiagnosis and overtreatment. The screening guide published by the World Health Organization in 2020<sup>2</sup> discusses the difficult trade-offs between benefits and harms as well as the ethical dilemmas faced by policymakers in deciding whether to implement cancer screening programmes in their countries.

## Governance of screening is complex and difficult to implement

In 2003, the Council of the European Union (EU) made recommendations on cancer screening, citing evidence that quality-assured, organised screening programmes in high-resource settings can reduce disease-specific mortality and be cost-effective. Based on the evidence at the time, the EU Council recommended screening for cervical, breast and colorectal cancers. Since then, research has continued to assess the benefits and harms of screening for other types of cancer. However, although the evidence base has grown, there is still no clear evidence to support countries embarking on population screening for other

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cancers and the position of WHO and EU Council at the time of writing remained unchanged.

Despite an evidence base that does not support such practices, there is a great deal of opportunistic screening carried out across Europe. Commercial drivers play an important role in promoting screening practices that may do more harm than good.<sup>8</sup>

“cultural capture can result in diversion of resources

Commercial drivers of screening can operate through different actors or parts of the health care system. Physicians, scientific societies, health care and patients' organisations, insurance bodies and policymakers may all be exposed to commercial drivers. A more recent development is the direct marketing to consumers of screening tests. Commercial drivers may operate through financial incentives, influencing the Research and Development (R&D) agenda, creating a culture that promotes the rapid adoption of new technologies, or lobbying and marketing aimed at clinicians and consumers.

Commercial drivers to screen for conditions with little evidence of population benefit present health care systems with a particular challenge. Not only can very large numbers of people be drawn into unevidenced screening programmes, but resources can be diverted from those who require medical advice and treatment. Overdiagnosis presents a particular issue, as at an individual level it is not possible to determine whether a cancer will progress, thus healthy people may be subjected to potentially unnecessary diagnostic procedures and treatment with the consequent risk of adverse effects. Thyroid screening, which has no evidence of population benefit but considerable evidence of overdiagnosis<sup>9</sup>

is an example of opportunistic screening that has seen a particular growth in recent years in Europe.<sup>8</sup>

Although it is recognised that screening is most effective when organised as a programme, much screening across Europe remains opportunistic, with patients being offered screening when they visit the doctor for other purposes. Occasionally, doctors' belief that screening is a good thing may be in part be the result of commercial drivers, such as the influence of firms promoting screening technologies, or sometimes the direct economic benefit they might gain. Furthermore, private sector clinics and laboratories as well as diagnostics' manufacturers seek to generate a commercial market for screening services and this presents another governance challenge. Even in countries where public health care systems have adopted a programmatic approach to screening with rigorous processes of quality assurance (e.g., in the United Kingdom and the Netherlands), these governance mechanisms may provide limited or no oversight of commercial screening. Such regulatory challenges are heightened by the rapid pace of technological change in cancer screening.

### Industry is driving a new wave of screening innovation

The first wave of cancer screening tests was largely developed in the public sector and promoted by charities and professional bodies. There is a new wave of cancer screening innovation and much of it originates in the private sector and is often supported by professionals. Diagnostics firms have become important actors in the promotion of new screening technologies, sometimes acting alone and sometimes in concert with established actors (i.e., charities, professional bodies, key opinion leaders and policymakers). Commercial service providers – private laboratories and clinics – may seek to build a bigger market for screening services by offering new technologies (such as 3D mammography) or expanding into disease areas not covered by national programmes, and this in turn may increase public demand and intensify the political pressure for adoption within public health systems.

In recent years, cancer screening has been the focus of much commercial excitement, with industry analysts predicting the potential for “drug-like blockbuster revenues”.<sup>10</sup> Firms that are developing new liquid biopsy-based cancer screening technologies have attracted huge billion-dollar sums of private investment. These firms are often investing large amounts on R&D, and as with the pharmaceutical sector, the corporatisation of screening-related research creates two dangers:

- clinical studies that lack the rigour to fully and accurately test the harms and benefits of the technology, and
- the capture of key opinion leaders through research collaboration with industry.

This new wave of molecular diagnostics firms are not only investing in research, they are also spending heavily on the promotion of their products. There is evidence that the new generation of molecular screening tests are marketed using strategies taken directly from the pharmaceutical sector: recruitment of key opinion leaders, direct-to-consumer advertising, physician detailing, and funding of NGOs including patient organisations to provide seemingly independent lobbying for government adoption of new technologies.<sup>7</sup> There is also evidence of astro-turfing – the creation of fake NGOs solely to promote the manufacturer's test.<sup>8</sup> This increase in marketing expenditure reflects a broader trend in the health care sector.<sup>8</sup>

As with all health care marketing, there is the danger that the commercial drive to generate revenues will lead to distorted messaging that presents a highly partial view of the evidence, biased towards potential benefits, obscuring potential harms, and resulting in unnecessary public expenditure. Carefully crafted PR strategies can ensure media coverage that reinforces this unbalanced picture; O'Keefe et al.,<sup>10</sup> have demonstrated that media coverage of new technologies for early disease detection, such as liquid biopsy molecular tests, 3D mammography and artificial intelligence-based detection, is skewed heavily towards reporting benefits and mostly fails to report conflicts of interest.

The lack of balanced media coverage can impact not only public perceptions but those involved in making decisions about the funding of biomedical research and clinical care, exacerbating cultural capture. Here we refer to the huge enthusiasm for innovation and notably the idea of personalised or precision medicine, rooted in the longstanding belief that genomics will revolutionise the practice of medicine, and now augmented by a faith in the transformative potential of digital technologies, including artificial intelligence. Public policymakers are prone to this form of cultural capture which can have two potential negative impacts on public health, including:

- a willingness to embrace new technologies because they are believed to represent the future of health care, without robust evidence that they improve clinical outcomes, and
- a misallocation of research resources, as funding flows to the discovery and development of new technologies, at the expense of simpler incremental improvements in the delivery of care, such as improving rapid diagnosis for patients presenting with potential cancer symptoms.

Lastly, cultural capture can result in diversion of resources to unevidenced large scale screening programmes and significant opportunity costs. Not only can it be wasteful of resources, but in countries with shortages of skilled technicians in areas such as imagery or endoscopy, it exacerbates these shortages resulting in delays in diagnosis in symptomatic individuals and growing inequality favouring those having access.

### The consumerisation of health care further drives screening

The landscape of commercial screening provision is being transformed not only by innovation in diagnostic technologies but by the broader development of the internet as a new mechanism for the consumerisation of health care. Direct-to-consumer testing services sold via the internet have been the target of regulatory action in recent years. An investigation in 2010 by the US Government Accountability Office<sup>11</sup> revealed the profound limitations of polygenic risk

scores\* offered by consumer genetics firms, resulting in regulatory action by the United States Food and Drug Administration (FDA), most notably when it shut down the testing service of industry leader 23andme.

“much screening across Europe remains opportunistic”

More recently, the Silicon Valley firm Theranos was closed down after revelations that its core technology did not work and its clinical laboratory had sent out thousands of incorrect results. Theranos had promised a preventive health care revolution, based on earlier detection of disease through the routinisation of testing for common disease markers. The huge sums invested in the firm demonstrate the continued promise of early detection, and a number of new firms have stepped into the space created by the closure of Theranos. The new European Union In Vitro Diagnostics (EU IVD) regulation will create a stricter regulatory environment for consumer diagnostic devices, but policy responses to the growing consumer market are likely to vary across European countries, given that within the EU regulation of consumer health care remains a Member State competency. Nevertheless, there is scope for coordination across countries, not least in monitoring what is increasingly an international market.

### Conclusion

In countries that have adopted a programmatic approach, cancer screening might be considered a paradigm for an evidence-based approach to health care, backed by a systematic approach to quality management. Yet it remains open to commercial pressures. The growth of screening governance mechanisms is a countervailing power to the increasing scale and scope of commercial influence,

\* These represent the total number of genetic variants that an individual has to assess their heritable risk of developing a particular disease.

but policymakers face fresh challenges as ever-greater volumes of private capital are invested in technological change and the push towards consumerisation.

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# NON-PHARMACEUTICAL TECHNOLOGIES IN CANCER CARE: FOR PROFIT OR FOR PATIENTS?

By: Richard Sullivan, Christopher M. Booth and Ajay Aggarwal

**Summary:** Non pharmaceutical technologies (NPT) in cancer are a growing and significant burden on health system costs. This domain of technology in cancer covers a huge range of non-pharmaceutical areas from artificial intelligence, mHealth technologies, diagnostic testing platforms, imaging, radiotherapy and surgery, among others. These rapid advances are heavily driven by commercial incentives. However, for many NPT within cancer care systems we are rapidly hitting the “break-even point” when additional costs of providing new technologies with small benefit causes more harm than good by diverting resources and efforts from ensuring broad access to the interventions which are known to have large benefits.

**Keywords:** *Non-pharmaceutical Technologies, Robotics, Commercialisation, Cancer*

## Rapid advance of technology in cancer research

The last two decades have witnessed an explosion of non-pharmaceutical technologies (NPT) in cancer care. These advances cover the full spectrum of domains from companion diagnostics (imaging, pathology) through to therapeutic innovations in applied surgery (robotics, minimally invasive, etc.) and radiotherapy (e.g. proton beam therapy, stereotactic body radiotherapy (SBRT)). A staggering 64% of cancer research papers from Europe in 2017 had some form of NPT at their core.<sup>1</sup> Meanwhile, in a recent review of the 150 most important cancer research questions, 149 concerned some form of NPT.<sup>2</sup> Research agendas driven by high income countries have led to an ecosystem which is dominated by ‘high tech’.

This, of course, is in the context of an even greater surge in pharmaceutical technologies, i.e. new cancer medicines and associated biomarkers.

The latest review of future research innovations by the Cancer Moonshot 2020 program created a top 20 list of some of the most advanced technologies.<sup>3</sup> For example, liquid biopsies, Artificial Intelligence (AI)-coupled to imaging and radiotherapy planning, embedded sensors, as well as ‘next generation’ radiotherapy and robotics. The traditional hegemony of pharmaceuticals in the European technospace is now being challenged by precision surgery including iKnife (diagnostic surgical scalpel), nanorobotics and radical new applications of computing to cancer diagnostics (e.g. Google’s DeepMind).

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Overall, cancer NPT has become a ‘Trojan horse’ for science and technology; there are few spheres of technology that cannot be applied to cancer care.<sup>4</sup> Neoliberal policies that favour the commercial sector above the public have also dictated national policy agendas.<sup>5</sup> The commercial imperative has created an ecosystem where NPT innovation (typical for-profit) takes primacy. In many instances this has led to value creep whereby NPT innovations lead to incremental improvements.

“Neoliberal policies that favour the commercial sector above the public have also set national policy agendas

### Ecosystems of NPT

The commercial determinants of NPT are being played out across three major ecosystems – diagnostic (molecular pathology), radiotherapy and radiology (including novel imaging technologies) and surgical (especially robotics but also in minimally invasive surgery). According to Statista global, NPT revenue is now over USD 380 Billion per annum, rising to a projected USD 600 Billion by 2024. On the one hand, some NPT have driven better outcomes (e.g. Intensity-modulated radiation therapy (IMRT) and Image-Guided Radiation Therapy (IGRT)); however, the benefits of these technologies are unevenly distributed within and between European Union (EU) countries and populations (particularly for the poor, older people, and ethnic minorities). Analysis of direct cancer expenditures across Europe has found, particularly in lower Human Development Index (HDI) Member States, significant over-spend on

low impact NPT, and underspend on basic, high impact ones, leading to a dangerous disconnection between cancer-expenditure and outcomes.<sup>6</sup>

As proposed by Woolf and Johnson, in all fields there is a “break-even point” when the additional costs of providing new technologies with small benefit may cause more harm than good by diverting resources and efforts from ensuring broad access to the interventions which are known to have large benefits.<sup>7</sup> An emerging issue in all countries is the perception, misled by media hype, that the latest technologies provide some miraculous route to cure, irrespective of the clinical facts.

### Da Vinci Robot: the archetype of NPT

Few technologies better represent the commercialisation of NPT than the Da Vinci Robotic Surgical System. This device, which allows surgeons sitting at a console to operate remote-controlled arms for minimally invasive surgery, was first given approval by the US Food and Drug Administration (FDA) in 2000. It had been expected that its inherent advantages, including improved visualisation of the surgical field, enhanced range of motion of the robotic arms and improved ergonomics for the surgeon, would translate into improvements in patient outcomes. However, in the case of prostate and rectal cancer, no improvements in functional or oncological outcomes have been observed. Despite the lack of clear evidence for its superiority over open and laparoscopic techniques and its higher associated costs (up to four times more expensive), it has undergone rapid adoption across Europe, even penetrating many middle income countries.<sup>8</sup> It could now be considered the cornerstone of surgical treatment for prostate cancer in these countries with increasing utilisation across tumour types despite the lack of level one evidence. Studies have demonstrated that the uncoordinated adoption of new technologies in health systems has created a socioeconomic differentiation in access to cancer care.<sup>9</sup>

Moreover, for example, in the United Kingdom where health care is free at the point of use, the commercial drive for

centres to adopt Da Vinci led to significant bypassing of local centres by people wishing to access this novel treatment. Men who sought out this NPT were younger, fitter and more affluent.<sup>10</sup> This provides some evidence that the European geographical variation in the availability of new “innovative” technologies within health systems, means that those patients with greater financial or physical resources are more likely to access them even across-national boundaries, creating profound inequities in access and outcomes.

### Hitting the ‘break-even point’ in NPT

It is increasingly clear that we have hit a break-even point in commercially driven research in cancer where effective innovation is less important than improving the fidelity with which all these technologies are delivered, i.e. the extent to which European health systems provide equity in access to the interventions they need, precisely when they need them.<sup>11</sup> We still fail to either provide access to NPTs that we know improve outcomes for patients or with the required quality assurance. In this regard it is idealistic to expect private industry to retain a public health perspective, when other priorities influence their resource allocation decisions. The commercial sector is accountable only to its shareholders and investors. Fundamentally, it is European governments that are responsible for putting in place the mechanisms, including health technology assessment processes that cover both pharmaceutical and NPT, to reward NPT that delivers clinically meaningful benefit at a fair price. Markets respond to externalities, and it is our view that the failure to deliver cancer NPT with significant value is a shared problem, with the bar for market entry set so low that capital funding for research and development of low value NPT is too easy to obtain.

The failure of the private sector to drive up the value offering for NPT for cancer is reinforced by weak federal governance mechanisms and a public European research funding environment that myopically focuses on innovation with little consideration for implementation, services and systems research for NPT.

Whilst guidelines have been created to improve the rigour of evidence collection, particularly for medical devices prior to implementation, a major factor influencing the type of study performed is the regulatory requirements of different health technologies prior to regulatory approval. Regulatory approval for a new medical device or technology requires clinical data, and a demonstration of its safety, prior to putting the device on the market. By comparison, systemic therapies need to go through the complex process of demonstrating superior efficacy compared to current standards of care.<sup>11 12</sup> This in part explains the paucity of randomised controlled trials for medical devices.<sup>13 14</sup> For example, only 5% of all research outputs in radiotherapy relate to clinical trials. However, the recent Cumberledge review highlighted the devastating impact of integrating drugs and devices without careful and robust evaluation of the impact on patients with respect to safety and health benefit. Unfortunately, the design of studies used for evaluation of new technologies are often lacking in rigour yet may form the basis for clinical implementation with retrospective single-centre case series (a low evidence standard) still dominating the literature.<sup>14</sup>

“allowed evidence-based medicine in cancer to be hijacked by using technologies with marginal effectiveness but maximum cost

Part of the explanation for hitting the break-even point now is that the business models at the heart of the European innovation systems – profits without prosperity as Lazonick describes it<sup>15</sup> –

### Box 1: Policy interventions to reduce inequalities in access to affordable and necessary cancer technologies

1. Build a culture of funding effective and affordable technologies: this is around re-orientation of public funding for research that builds orphan technology domains e.g. automation in radiotherapy workflows, virtual reality enhanced surgical training, mHealth and self-management referral systems. But this needs to come with building momentum in key NPT domains, e.g. pathology and surgery, as well as creating a policy dialogue that such approaches are not ‘second class’ technology and medicine.
2. Coupled to cultural re-engineering, there is a need to hold NPT to high levels of evidence. We need trials/well conducted studies to show NPT have benefit AND we need the magnitude of benefit to be meaningful (i.e. not trivial). This needs to be coupled to a willingness to de-implement new tech when future evidence shows it may not work as well as we once thought.
3. Audits to ensure gaps in access and quality from proven innovation are managed to maximise outcomes. With this public reporting of outcomes and benchmarking of best practice, one can identify optimum processes for delivery and support rapid knowledge transfer and uptake of high value NPT.
4. Pricing and reimbursement: a wide range of supply and demand side policies are needed to manage technologies, with a specific focus on value-based payment systems and health technology assessment programs for all technologies.
5. Public and Patient engagement: a new narrative is necessary to balance out the unrelenting personalised-medicine and ‘access to everything for everyone’ mantra. Technology is not a ‘bypass’ for better governance in the face of clinical, and systems failure, nor for the lack of human resources.

are not fit for purpose. Yet, turning this around will be profoundly difficult. As one surveys the wider cancer technology landscape, especially in the ‘new’ digital world of AI, the commercial actors have become, arguably, far more diverse and powerful. NPT in cancer has never been more profitable and AI is now the new ‘precision’ cancer medicine. However, our own clinical community must also shoulder a significant portion of both the blame and the solution. As Ioannides noted, medicine and health care are wasting societal resources because ‘we’, clinicians, have allowed evidence-based medicine in cancer to be hijacked by using technologies with marginal effectiveness but maximum cost.<sup>16</sup>

### Policy interventions to manage NPT

Industrial and macroeconomic policy frame much of the impact of NPT on cancer control, and it remains an open question whether political elites and

clinical communities have the will or appetite to embrace different paradigms. This is especially so when more and more of health care is being delivered in mixed market economies with unregulated private sectors, and underinvested public systems.<sup>17</sup> The impact of this is crystal clear; poor and unequal outcomes coupled with declining value, of which very high cost (and in many cases unnecessary) NPT constitute a substantial part of the problem. So what could and should be done?

On the one hand, in many European countries there remains a failure to ensure universal health coverage or the rational allocation of limited resources to key modalities and site-specific cancers. On the other hand, governments are engaging in *ad hoc* funding of expensive pharmaceutical technologies and/or NPT in the absence of basic radiotherapy provision or adequate surgical capacity. This is a massive political failure at

national and supra-national levels. However, to rectify these intrinsic flaws there are a number of possible policy interventions aimed broadly at reducing inequalities in access to affordable and necessary cancer technologies as well as addressing technology-induced inequalities (see Box 1).

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## A short guide to cancer screening. Increase effectiveness, maximize benefits and minimize harm

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**Freely available for download at:** <https://www.euro.who.int/en/health-topics/noncommunicable-diseases/cancer/publications/2022/a-short-guide-to-cancer-screening.-increase-effectiveness,-maximize-benefits-and-minimize-harm-2022>

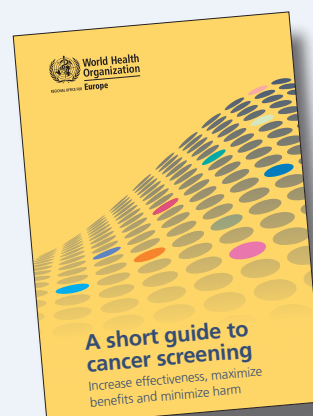
The purpose of cancer screening tests is to detect pre-cancer or early-stage cancer in asymptomatic individuals so that

timely diagnosis and early treatment can be offered, where this treatment can lead to better outcomes for some people.

The aim of a cancer screening programme is either to reduce mortality and morbidity in a population by early detection and early treatment of a cancer (for example, breast screening) or to reduce the incidence of a cancer by identifying and treating

its precursors (such as cervical and colorectal screening).

This short guide is designed to be a quick reference that contains the important ideas about cancer screening. Readers should refer to other publications for comprehensive discussion and detailed guidance on cancer screening programmes.



# COMMERCIAL DETERMINANTS OF CANCER MEDICINES

By: Christopher M. Booth, Ajay Aggarwal and Richard Sullivan

**Summary:** Europe is experiencing a ‘value crisis’ for cancer medicines. Whilst some therapeutic innovations have delivered substantial clinically meaningful benefits, many new cancer drugs benefits are marginal. At the same time prices (and overall costs) have dramatically increased. The reasons behind this are multifactorial. Multi-level intervention including changing the narrative of patient organisations, altering the clinical communities acceptance of poor quality clinical trials, integrating socio-economic studies, requiring a balanced portfolio approach from public funders, raising the regulatory requisites and embedding health technology assessment will all be needed to ensure valuable, sustainable and equitable cancer medicines.

**Keywords:** Cancer Medicines, Public Investment, Health Technology Assessment, Value

## Introduction

In the last decade, cancer drugs have become the main focus of research, clinical care and health budget spending across Europe.<sup>1</sup> The molecularisation of cancer in terms of understanding it through molecular-level factors such as genes and hormone receptors rather than environmental or behavioural factors, has led not just to its pharmaceuticalisation<sup>2</sup> but also to medicines gaining a dominant position in the social psyche of cancer care.<sup>3</sup> Oncology as a domain has reversed decades of productivity decline in the biopharmaceutical industry, leading to extraordinary returns on investment. But this has come at a cost. Whilst a range of new cancer medicines, notably in the immuno-oncology class, have added substantial clinically meaningful benefit, many have not. Moreover, even among those medicines which do appreciably improve outcomes, their prices (and overall therapeutic costs – diagnostics,

toxicity management, etc.) are posing inherent risks to a system which unduly rewards low value cancer drugs.<sup>4 5</sup>

Here we explore the concepts of value in cancer care, current spending on cancer medicines, lessons from trials and routine clinical practice. These concepts can provide insight into whether private sector commercial interests can co-align with public sector interests or whether their diverging trajectories pose a significant threat to Europe’s future ability to deliver equitable and affordable cancer care.

## The Problem with Value

The oncology community currently faces a crisis in the way the value of cancer medicines is interpreted. Clinicians conceptualise value as the relationship between magnitude of benefit (net of side effects) and costs.<sup>6</sup> The numerator (i.e. magnitude of benefit) represents the interface between the measure which

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is improved (i.e. overall survival (OS), quality of life (QOL), or alternative endpoints) and the magnitude of improvement (i.e. effect size). Given that the goal of any medical intervention is to help patients live longer and better lives, the primary endpoint of all oncology trials should be OS and/or QOL. Yet, the oncology community has widely embraced the concept of “surrogate” endpoints; predominantly progression-free survival (PFS).<sup>7</sup>

“rushing to embrace early access schemes despite their well known drawbacks”

PFS is a composite endpoint representing time to tumour growth on imaging and/or death. It was initially designed as an intermediary endpoint to guide decision-making for early phase trialists in identifying which compounds to move from phase I/II to phase III testing. It was not originally intended to be an endpoint that should influence clinical care. However, over the past two decades, it has become the most common primary endpoint in oncology randomised controlled trial (RCTs) as its use dramatically shortens duration of clinical trials and recruitment numbers.<sup>8</sup>

While there are a handful of circumstances in which PFS is known to be a valid surrogate for OS, this represents a small minority of contexts in which it is used.<sup>9</sup> Most contemporary oncology RCTs either do not measure OS or find no benefit in OS. Accordingly, we find ourselves in a scenario in which most new cancer medicines are known to shrink tumours on imaging but likely do not help patients live longer lives. It has also been shown that PFS is not an appropriate surrogate

### Box 1: The UK Cancer Fund

A special body called “The NHS Cancer Drugs Fund” (CDF) was established in the UK in April 2011, as result of patient association advocacy, to improve access to cancer drugs. The CDF had a budget to provide funding for orphan indications or rare conditions that NICE would ordinarily not appraise.<sup>10</sup>

The CDF had an initial budget of €50 million per annum with the plan to move towards a value-based pricing scheme by 2014. The fund benefitted over 95,000 patients, with its budget reaching €200 million in 2011/2012 and €340 million in 2015/2016 following public pressure demanding access to new cancer medicines.<sup>11</sup>

Economists established that the fund diverts NHS money to cancer, irrespective of the low survival rate of some drugs.<sup>12</sup> A study published in 2017 revealed that the CDF had not delivered meaningful value to patients. Since its creation, out of 47 CDF approved indications, only 18 (38%) showed a statistically significant OS benefit, with an overall median survival of 3.1 months. With very minimal or no benefit in survival, most of the drugs did not reach the threshold of meaningful clinical benefit and indeed NICE had previously rejected 26 (55%) of the CDF approved indications because they did not meet cost-effectiveness thresholds.<sup>13</sup>

As the fund failed to provide meaningful value to patients, it was merged with NICE.<sup>14</sup> This example shows that reacting to lobbying efforts without informed analysis of the drugs can create negative consequences. Better-informed pressure from patients and professionals would have saved a large amount of money which could have been allocated to supportive care for cancer patients (psycho-social support) or to other diseases.

By: Jeanne Riqué and Marily Corbex

for QOL.<sup>10</sup> Even among those new cancer medicines which do improve OS, the average gains in survival are very modest.

### Price of Cancer Medicines

While the numerator (i.e. effect size) of new medicines is small, the denominator (i.e. price) is staggering. The prices of cancer medicines impact at two levels. First, in health systems without universal coverage they can lead to serious out-of-pocket expenditure (financial toxicity) that generates dramatic inequalities. In addition, at the societal level, the impact on health and cancer budgets leads to opportunity costs which can ‘crowd out’ funding for other areas of cancer care. Even if a cancer medicine is cost-effective, it may be unaffordable.<sup>15</sup> The commercial model that delivers low-value, high-priced cancer medicines also incentivises poor drug development. Thus the commercial aspects of cancer medicines are, from an economic perspective, intimately linked to all the technologies we use in

cancer care. The average annual price for a new cancer medicine is rising rapidly and now approaches \$150,000.<sup>16</sup> It is now well established that private sector investment in research and development cannot explain these prices. Making the high prices even more problematic is the observation that there is no relationship between the magnitude of benefit and price within the cancer medicine ecosystem and where prices increase over time despite a supposedly ‘competitive’ environment.<sup>13</sup> The current approach to cancer drug pricing appears to be driven not by any rational economic policy, but by the upper bounds of what the market will bear, even in times of financial crisis.<sup>14</sup>

### Regulatory and Political Challenges

In most countries and regions of the world, including in Europe, governance mechanisms to increase the value of cancer medicines are insufficient. Health technology agencies have struggled to maintain a high enough bar in the face of

political pressure. And where they have achieved this, e.g. the United Kingdom's National Institute for Health and Care Excellence (NICE), political expediency, and lobbying using the narrative around ensuring better and quicker access to medicines has created bypass mechanisms such as the Cancer Drugs Fund in the UK that has led to massive financial losses (see Box 1).<sup>15</sup> The lessons from the first iteration of the Cancer Drugs Fund have not been translated internationally; with new plans to facilitate early access to drugs that have not even received regulatory approval but are considered “promising,” many European Union countries are rushing to embrace early access schemes despite their well known drawbacks.

Such ease of market access and rapid clinical development and entry into markets has meant that among the world's ten largest pharmaceutical companies, revenues generated by sales of cancer medicines increased 70% between 2010 (\$56 billion) and 2019 (\$95 billion) while revenues from other medicines decreased by 18% (from \$342 to \$282 billion). The European biopharmaceutical sector, supported by federal and philanthropic funders who have significantly aligned their budgets to focus on basic cancer sciences and cancer medicines, has dominated the European Research Area since its inception. From a societal perspective, it is worth considering that population-level European cancer health outcomes are unlikely to improve given the focus on the metastatic disease, with many new cancer medicines delivering less than 2–3% of survival benefit. Many policy discussions have lost the wider perspective, including QOL, socio-economic impacts, and other key dimensions.

### A Research Ecosystem that is Not Delivering Value

Observations from the cancer research ecosystem offer critical insights into the current low-value cancer medicines crisis. Our group has tracked temporal trends in industry-sponsored oncology RCT design and results since 1975. Among trials of

cancer medicines in breast, non-small cell lung, and colorectal cancer foundational changes, include:

- 1) a shift away from government funding towards industry (which now funds ~90% of all cancer drug RCTs);
- 2) a massive increase in sample size (with the resulting statistical power to detect a very small difference between treatment groups);
- 3) a shift away from overall survival as the primary endpoint (PFS is now the endpoint in ~40% of RCTs compared to ~30% for OS); and
- 4) among those trials which do show improved OS, the gains are modest with average improvements in median survival of two to three months.

Data from the global landscape of cancer RCTs show that 87% of all cancer RCTs test medicines rather than new surgical or radiotherapy techniques. For Europe, this means that patients are not receiving treatments and systemic therapies that we know work, i.e. there are implementation and access barriers to evidence-based care. This needs parallel investment in understanding the drivers and necessary improvements on a health system level.

“policy discussions have lost the wider perspective, including quality of life and socio-economic impacts”

### Real-world data is not a Panacea

Is public sector real-world data (RWD) a panacea for making up for the failure to design and deliver marketing authorisation trials that produce data that can determine whether a medicine delivers clinically

meaningful benefit? While there are many important uses of RWD (i.e. to understand access, quality, outcomes), the growing movement towards using RWD for regulatory decision-making and even as a replacement for the RCT is very concerning and may lead to the adoption of cancer medicines with little benefit and perhaps even net harm.<sup>16</sup> Our group recently reviewed all RWD studies (n=293) for cancer drugs approved by the United States Food and Drug Administration (FDA) and European Medicines Agency (EMA) during 2010–2015.<sup>16</sup> Some 78% of these studies were of low methodologic quality. Most studies (63%) reported inferior survival in routine practice compared to the relevant RCTs; RWD studies that reported superior outcomes to RCTs (which should be viewed with great scepticism based on everything we know about the efficacy-effectiveness gap) were most likely among low-quality studies of RWD.

### Solutions

The private sector now determines nearly the entire biopharmaceutical (cancer medicines) ecosystem across Europe, for which it enjoys massive public sector research funding alignment. Whilst this certainly provides certain European countries (including the UK) with competitive, wealth-generating cancer research economies, as well as some truly novel cancer medicines that deliver clinically meaningful benefit, our assessment is that, overall, the commercial determinants of cancer medicines in both research and care are creating an unsustainable situation both in terms of delivering better outcomes and more affordable, equitable cancer care systems. So, what are the solutions?

First, Member States must introduce high standards, both at the national level and through stronger health technology assessment mechanisms, coupled with more sophisticated pricing and reimbursement systems. But at the heart of this is a cultural change required in clinical/medical oncology that no longer accepts poor quality clinical trials, that does not engage in the hype surrounding some new medicines and pursues fair prices as a central tenant of clinical

care. A new contract with private sector interests for cancer medicines must also include the major federal and philanthropic research funders and better national policy around the choice architecture of payment systems. Our data show that their respective research portfolios are massively un-balanced.<sup>20</sup> More funding needs to be re-allocated to the public sector, investigator-driven medicines research and trials, health services and systems research as well as a major drive to integrate socio-economic studies into clinical trials of medicines. These multi-level actions are essential if valuable commercially-driven cancer medicines research is to deliver better, more equitable and affordable care across Europe.

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## Screening: When is it appropriate and how can we get it right?

**By:** A Sagan, D McDaid, S Rajan, J Farrington, M McKee

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Technological and other scientific advances have made it possible to screen for ever larger numbers of molecules and see inside the human body with a level of detail that was once unimaginable. Where there is good evidence that detecting a condition early will, overall, be beneficial for those who are screened, then it may be appropriate to design and implement a formal screening programme.

However, just because something can be done does not mean that it should be done as screening may bring benefits as well as harm. In this brief the authors start by explaining the core components of a screening programme, highlighting that, while seemingly simple, putting together all elements of a screening programme is very complex.

They then ask when screening should be done, emphasizing the continued relevance of Wilson & Jungner's screening principles. In addition, they examine the pressures to implement screening and, where screening is inappropriate, suggest ways to reduce it. When screening is appropriate,

evidence is presented on how to achieve optimal results. This brief is an essential reading for anybody involved in the decisions on screening or its provision.



# COMMERCIAL AND SOCIAL DETERMINANTS IN PALLIATIVE CARE

By: Stein Kaasa, Marianne Jensen Hjermstad and Per Sjøgren

**Summary:** All cancer patients benefit from structured palliative care interventions that are patient-centred, as these demonstrate improved care quality, symptom relief and quality of life. Patient-centred palliative care should be provided alongside tumour-centred care (TCC), rather than the sole TCC-focus on cure supported by the pharmaceutical industry. In practice, this is not the case. Commercial determinants are a prohibitive factor for the integration of patient-centred care (PCC) and TCC. The time has come for joint actions by politicians, the medical industry and professional organisations to consolidate palliative care and PCC as essential parts of cancer care, with the aim of improving quality of life.

**Keywords:** *Palliative Care, Patient-centred Care, Integration, Commercial Determinants, Symptom Management, Quality of Life*

## Introduction

The 1990 World Health Organization (WHO) definition of palliative care emphasised the active approach of palliative care for symptom control in patients with progressive, far-advanced disease and limited life expectancy. Since 2002, subsequent WHO definitions have explicitly recommended the provision of palliative care from early on in the disease trajectory regardless of treatment intention,<sup>1</sup> a request that has not been accomplished. The World Health Assembly resolution on palliative care in 2014 urged national authorities to improve access to and develop palliative care as a core component of health systems. Unfortunately, palliative care is still misconstrued as end-of-life care

only, and is seen as being passive and “not offering hope”, publicly, politically and within health care.

Palliative care is active care, with interventions and examinations that address the needs of patients and families during curative, life-prolonging and end-of-life care. Patient-centred care (PCC) is the mainstay of palliative care, focusing on the *patient*, not the disease. The aim is to provide the best possible symptom relief; physically, psychologically and existentially, and to improve quality of life (QoL). This is achieved by acknowledging the patients’ perceptions and preferences, with early, systematic assessments and treatment. The multidisciplinary approach makes palliative care applicable at all health care levels, corresponding to the

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**Table 1:** Stakeholder opinions on the commercial and social determinants of health in cancer care

Negative or imbalanced consequences – four main categories	Negative or imbalanced consequences – continued
<p><b>1. CDoHs shape today's anticancer treatment and highly influence cancer care</b></p> <ul style="list-style-type: none"> <li>Economic power and resources of the pharmaceutical industry           <ul style="list-style-type: none"> <li>permits extensive marketing of drugs, conduct of treatment trials</li> <li>constant promotion of new, expensive drugs, driving costs and demands</li> <li>continuous development and promotion of new treatments and technologies, i.e. (drugs, radiotherapy, imaging, surgery)</li> <li>constantly promoting new methods as better and more efficient than well-known technologies</li> <li>deliberately underscoring that most of these new, advanced therapies are effective only in highly selected subgroups of patients</li> </ul> </li> <li>Patent protection issues delay bio-equivalent products, driving costs up           <ul style="list-style-type: none"> <li>pushing new patented drugs limits access to efficient medications</li> <li>non-patented, traditional agents launched in new patented formulas</li> </ul> </li> </ul>	<p><b>4. Unfavourable marketing of anticancer drugs</b></p> <ul style="list-style-type: none"> <li>Present regulations of industry-driven marketing remain inadequate           <ul style="list-style-type: none"> <li>Imbalanced marketing of expensive drugs with inflated cure rates</li> <li>Undermining the fact that some drugs are for selected populations only</li> <li>The constant drive to expand the indications for several drugs</li> <li>Private companies offer new, often unproven treatments for out-of-pocket payment with high promises, increasing the public demand</li> </ul> </li> <li>Extensive marketing of expensive analgesics with no superior effects compared to affordable and well-tolerated morphine</li> <li>The dominating marketing of analgesics may downplay efficient pain interventions, such as single fraction radiotherapy when indicated</li> <li>No ethical imperative to produce low-cost morphine to increase availability</li> </ul>
<p><b>2. A steadily growing and dominating focus on cure</b></p> <ul style="list-style-type: none"> <li>A gradual medicalisation of the society at large, with social issues becoming medical issues, as well as in health and end-of-life care with a general marketing of staying young and healthy forever</li> <li>Most of today's medical funding, from governments, research councils and programs, EU and private charities use this assumption as a bait for funding           <ul style="list-style-type: none"> <li>marketing that most cancers can be cured</li> <li>little attention towards the heterogeneity of cancer diagnoses and patients</li> <li>neglect negative consequences of anticancer therapy at end-of-life</li> </ul> </li> </ul>	<p><b>Positive consequences – two main categories</b></p>
<p><b>3. Key CDoHs in PCC</b></p> <ul style="list-style-type: none"> <li>Commercial interests prevent implementation of PCC due to the dominant focus on antitumor treatment, new drugs and technologies</li> <li>Introduction of palliative and symptom-focused care occurs too late in the disease trajectory, due to more anticancer treatment at end-of-life</li> <li>Little attention to side effects during and after curative and life prolonging treatment</li> <li>Few economic incentives related to symptomatic management and psychosocial support</li> <li>Death and dying attract little attention compared to anticancer treatment</li> <li>Disproportionate focus, interest and cost allocation between TCC and PCC</li> <li>The paradox of the iatrogenic* opioid-overuse in some high-income countries alongside insufficient pain management and poor availability/accessibility in many middle and low-income countries</li> <li>Auxiliary palliative care consultations during pharmaceutical studies are not reimbursed as they are not part of the trials</li> <li>Palliative care still has a stigma: this is a CDoH enforced by the tumour-centred focus of cancer care, industry and media, influencing both health care professionals and the public</li> <li>The common perception that any physician/oncologist can provide specialist PCC</li> </ul>	<p><b>1. Substantial advances in cancer therapies</b></p> <ul style="list-style-type: none"> <li>The pivotal role of the pharmaceutical industry in the development of anticancer and symptom-relieving drugs leading to:           <ul style="list-style-type: none"> <li>substantially higher cure rates and extended life expectancy for millions of patients for many years</li> <li>better symptom management, tolerance to treatment, QoL and supportive care</li> <li>development of analgesics, antiemetics, antidepressants and cachexia<sup>†</sup> drugs (to some extent) have been favoured by industry, and improved symptom management and functioning</li> <li>world-wide opioid availability, albeit varied accessibility, availability and affordability across countries</li> </ul> </li> </ul> <p><b>2. Policy regulations and private initiatives</b></p> <ul style="list-style-type: none"> <li>Stronger enforcement of marketing regulations in the last two to three decades</li> <li>Privately run non-profit services and organisations contributing to better cancer care and research</li> </ul>

Source: Authors' own survey.

Note: Fifteen of 18 collaborators (83.3%) responded to this email survey.

\* Illness caused by medical intervention or treatment.

† a complex syndrome associated with an underlying illness causing ongoing muscle loss that is not entirely reversed with nutritional supplementation.

WHO statement that the competence, attitudes, and skills of palliative care should be integrated in cancer and general health care.<sup>2</sup>

“Patient-centred care is the mainstay of palliative care”

The dominating focus on medical advances, curation and prolongation of life has gradually increased and led to extended use of anticancer treatment even in advanced stage cancer and in the last weeks or days before death. The numerous cycles of anticancer treatment now being administered for most diagnoses have prolonged survival for millions of people. However, the quality of this treatment would have been substantially better, and more effective, if integrated with a palliative care approach.<sup>2</sup>

The documented evidence that integration of palliative care and PCC alongside tumour-centred care (TCC) provides considerable benefits in patient-centred outcomes is substantial. Adhering to the individual patient’s needs, experiences and own symptom evaluation results in better physical and emotional functioning, QoL and care satisfaction in patients and caregivers, reduces hospital admissions, and even prolongs survival time.<sup>2,3</sup> Still, referrals to palliative care occur far too late in the disease trajectory, and PCC and TCC are not universally nor systematically integrated. This does not comply with recommendations and guidelines from WHO, the European Society for Medical Oncology (ESMO), and the American Society of Clinical Oncology (ASCO).<sup>2</sup>

Commercial, financial, professional and attitudinal barriers hinder this integration. Partly driven by commercial and social incentives, budget allocations are markedly disproportionate, with substantial investments in TCC and anticancer treatment relative to PCC.

The estimated and considerable increase of patients living with cancer underscores the need for change to ensure high quality care to patients and families, acknowledging their voices. A better understanding of how the commercial and social determinants of health (CDoHs) influence the policy of cancer care is necessary. This should guide the development of a model with informed implementation strategies to integrate PCC and TCC, with joint actions by organisations (WHO, European Union), health care providers, the medical industry and politicians.

### Stakeholder opinions point to how CDoHs have influenced cancer care and palliative care

We surveyed members of the European Palliative Care Research Centre (PRC) in November 2021 about the commercial and societal determinants pertaining to cancer care, including survivorship care – “cured” or “living with cancer”, palliative care, and end-of-life care. Respondents come from a variety of countries, are renowned researchers, and represent a diversity of medical disciplines and related professions. All respondents have worked for decades in oncology, palliative care, internal medicine, anaesthesiology, neurology or public health. **Table 1** provides an overview of their responses to 24 open-ended questions or statements, divided into four main categories of perceived negative influences, and two about perceived positive influences.

### The influence of CDoHs on palliative care development and integration

#### Poor integration of PCC and TCC

Economic incentives have led to the development of anticancer treatments and advanced imaging technologies for diagnostics, cure and life prolongation. Examples are PET-scanning, cytotoxic targeted agents, immunotherapy and radiotherapy. The corresponding commercial interest in symptom-directed medications has been substantially lower; when present, the underlying intention is to relieve symptoms such as nausea, mucositis or neuropathic pain to increase the tolerance for more anticancer treatment. Thus, the main driver is still TCC, not PCC *per se*. One may actually

argue that the biased focus on new and advanced anticancer treatments totally sets the previously small economic momentum of PCC aside, commercially and publicly.

The assumption that by treating the cancer, the patient will improve is coupled with the similar impetus to treat as long as possible, even if detrimental to the patient. A large registry-based study showed that close to 20% of patients received chemotherapy the last two weeks of life.<sup>4</sup> For radiotherapy, the financial models incentivise provision of multiple rather than single fractions in patients with incurable metastatic disease and short life expectancy, despite strong evidence of equivalent outcomes, and substantial patient benefits.

To implement PCC, a shift of focus from solely anticancer treatment to the patient perspective and from commercial profit to quality care is necessary. The erroneous impression of PCC, palliative, supportive, survivorship and end-of-life care being self-financed, or at best only needing minor funding, must be challenged.

Moreover, the clever marketing of new anticancer treatments as personalised medicine given their association with certain biomarkers, promotes the impression that the patient is in focus. That is not the case: the tumour is the target. This TCC approach should be merged with PCC that is responsive to patients’ needs throughout the course of treatment. This integration of care actually benefits all parties, and should be promoted and anchored by commercial bodies, NGOs, professional organisations and politicians alike, enforced by adequate resource allocation at all levels.<sup>2</sup>

#### Pain management and use of analgesics

This is a clear example of poor universal and human outcomes when commercial interests set the clinical agenda. Commercial determinants have highly influenced the use of analgesics worldwide. In cancer care the pharmaceutical industry has been particularly involved in manufacturing and marketing opioids, which is the mainstay for achieving pain relief and improving the QoL for patients with cancer-related pain.<sup>5,6</sup>

The first decade of promoting the WHO pain ladder,<sup>9</sup> introduced in 1986, focused on the favourable analgesic effects of opioids in patients with advanced cancer and a short life expectancy. This contributed to substantially improved pain management in developed countries. Later, the extensive marketing by the pharmaceutical industry in high income countries has led to extended use of opioids for chronic non-cancer pain conditions. Despite the positive analgesic effects for many people, the detrimental effects associated with addiction became increasingly catastrophic over time. An opioid crisis became gradually apparent, with overuse, diversion of drugs, opioid use disorders, and huge numbers of overdose-related deaths particularly in the United States (U.S.). Paradoxically,

regulatory interventions to curb the epidemic also led to a substantial reduction in opioid use in cancer patients near the end-of-life, corresponding to an increase in pain-related emergency room visits.<sup>9</sup>

“Better models for cost containment are needed”

Commercial determinants are definitively in play concerning availability and affordability of analgesics in middle- and low-income countries. In many middle-

and low-income countries, patented opioid formulations with complex delivery mechanisms; i.e. transdermal patches and sustained-release formulations, are subject to intensive marketing to replace the simple, equally effective generic immediate-release morphine agents. Lack of access to morphine that is essential for relief of severe cancer related pain, causes enormous suffering.<sup>9 10</sup>

#### **Health care spending at the end of life**

The increased complexity and overall escalation of costs apply to end-of-life care. This is driven by high-technology interventions, intensive care and anticancer therapies, most with little benefit to patients. The use of these interventions were most pronounced in the U.S., enforced by marketing activities.

**Table 2:** Recommendations for improvement

Problem area	Operational recommendations
<b>Consensus-based health policy changes are lacking at all decision-making levels, including political, health care and hospital administration, professional organisations, journalists/press</b>	<ul style="list-style-type: none"> <li>• Key policy changes consisting of specific resource allocation, benchmarking and anchoring by responsible parties, policymakers and management at all levels to emphasise the importance of improving cancer care quality</li> <li>• Collaborative promotion of palliative care and PCC as an integrated part of quality cancer care</li> <li>• Provide reasonable resource allocation and financial incentives for delivery of PCC in any relevant setting</li> <li>• Provide incentives other than financial for delivery of PCC; i.e. accreditation programs</li> <li>• Establish firm collaboration between organisations, industry, universities</li> <li>• Promote plenary presentations of integration results at major ASCO and ESMO meetings</li> </ul>
<b>Commercial incentives drive medical and technological developments</b>	<ul style="list-style-type: none"> <li>• Regulatory bodies must take action to:               <ul style="list-style-type: none"> <li>– reduce biased marketing with promises not accounted for, i.e. inflated cure rates</li> <li>– open for more bio-equivalent drugs, esp. in underserved areas and countries</li> <li>– reduce financial incentives for intensive end-of-life care</li> </ul> </li> <li>• Pharmaceutical industry should be required to:               <ul style="list-style-type: none"> <li>– incorporate PCC in all clinical studies, without extra funding</li> <li>– invest in studies for regulatory approval of truly palliative indications</li> <li>– support and collaborate in non-pharmaceutical clinical studies</li> </ul> </li> </ul>
<b>The unilateral focus on cure (TCC) in medical school shapes the professional conduct, and creates attitudinal barriers that are reinforced in clinical practice</b>	<ul style="list-style-type: none"> <li>• Mandatory lectures on palliative care and PCC, in medical school/specialist training</li> <li>• Clinical rotations in palliative care clinics</li> <li>• Promote joint educational activities with other health care professionals to implement the human, person-centred perspective</li> <li>• Establish a medical palliative care speciality</li> </ul>
<b>The patient voice does not come across, not in TCC, often also not in PCC</b>	<ul style="list-style-type: none"> <li>• Make adherence to FDA's recommendations on PROMs mandatory in all cancer programs</li> <li>• Include PROMs in prognostic tools to increase precision prior to treatment decisions</li> <li>• Include PROMs results in drug marketing</li> </ul>
<b>Palliative care is misconstrued as end-of-life care only</b>	<p>This professional, societal and public opinion can only be reversed by</p> <ul style="list-style-type: none"> <li>• governmental and political initiatives, cognisance and incentives</li> <li>• inclusion in plenary and panel discussions at major professional conferences</li> <li>• emphasis in educational curricula</li> </ul>

Notably, overall end-of-life care spending did not differ much between the U.S., Canada and five European countries, with hospital care being the main driver of costs.<sup>11</sup> This calls for a change. In today's health care systems, public and private interests compete with one another, as well as with other factors. It's been documented that the probabilities of receiving chemotherapy outside clinical trials during the last month of life were substantially higher in comprehensive cancer centres, private for-profit clinics and centres with no palliative care units than in university hospitals.<sup>12</sup>

Systematic symptom assessment with patient-reported outcome measures (PROMs) is not implemented systematically in cancer care. This inherent part of PCC improves patient care, QoL and tolerance to treatment, is an inexpensive quality indicator and highly cost-efficient as it reduces unnecessary treatment and emergency admissions by 5% to 10%.

Better models for cost containment are needed to examine the societal and individual advantages and outcomes of less intensive anticancer treatment at end-of-life, and professional and societal barriers to palliative care must be challenged. The disproportionate budget allocation between anticancer treatment and palliative care is a major issue, with death and dying not being on the commercial and marketing agenda. A change is needed in the Western world as well as in low- and middle-income countries with poor or no palliative care or symptom relief.<sup>9 12</sup>

### Private health care services

In countries with mixed health provision, i.e. both state and private health care providers, some conditions may not be prioritised for state funding, nor requested, due to a lack of strong advocacy groups for very sick patients. The consequence is effective rationalisation to cut costs. Private providers frequently respond to these market mechanisms, leading to well-developed private oncology practices. However, private insurance companies are less forthcoming about providing private palliative care cover. As a result, the major part of the funding may come

from the charitable sector. Although this allows for a degree of independence and more flexibility in service developments, the funding is more unpredictable and scattered. Further, social inequities in access to palliative care may be reinforced by a higher degree of out-of-pocket payments, albeit also demonstrated as a scarce commodity in countries with national health care. With limited budgets, the never-ending focus on new and expensive drugs is detrimental to overall budgets, a fact that may have positive as well as negative implications for a given palliative care service.

Taken together, this calls for extensive collaborative efforts between industry and health care professionals towards the common goal, better care for cancer patients and families.

### Discussion and recommendations

Commercially and societally, it is easy to sell the message – *we will cure cancer*. This is obvious from the major financial contributions from the pharmaceutical industry to cancer hospitals, cancer societies and patient organisations. All bodies promote the cure message, appealing to human nature and emotional states; *“live as long as possible”*, *“I don't want to die”*. Rightfully so, huge investments in new drugs and technologies have led to major improvements in TCC, but not without costs. One is the abyss in the opioid situation with shortage and low access coupled with an overuse epidemic with soaring numbers of death. The intensity of anticancer treatment in the last weeks and days before death is another example, with little or no benefit to patients.

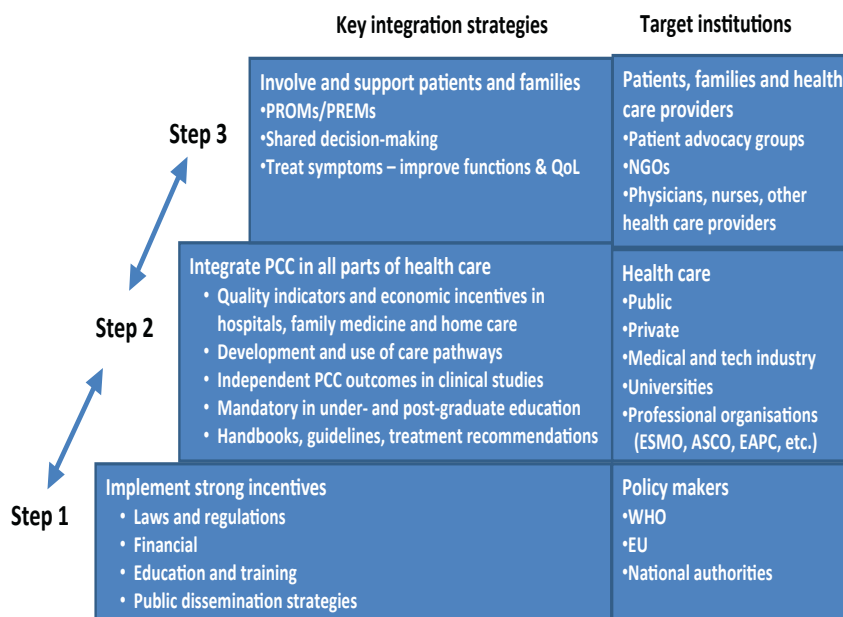
The unidimensional cure focus contrasts professionally endorsed treatment recommendations from ASCO and ESMO, as PCC is perceived as less important, and an add-on to TCC. This perspective disregards that patients and families want *“to live as well as possible”* in the time left. Yet, patients with incurable cancer often have a dual perspective, *“as well”* and *“as long”* as possible. These perspectives vary with disease stage, suffering and time (days/weeks/months) or personal milestones (e.g. living to see

a child's wedding). Provision of integrated PCC and TCC based on patient needs and mutual professional understanding should be mandatory during the entire disease trajectory, fulfilling the holy grail of palliative care; providing the best possible treatment and care to improve QoL, in supportive and palliative care. The key is a closer collaboration between the pharmacological industry and health professionals.

Societal and attitudinal barriers and the overarching perception of palliative care and PCC being synonymous to end-of-life care must be conquered. Palliative care carries a stigma, commercially, publicly, and in the press, that is reinforced by the professional socialisation throughout the medical and nursing education. Direct, targeted and collaborative initiatives are called for in all areas to improve, preferably supported by commercial incentives, policy regulations and mutual understanding among all involved (see Table 2).

A basic premise for integration of TCC and PCC is that PCC is prioritised in budgeting processes. Fixed reimbursements must be triggered and transferred automatically when PCC activities are implemented, according to specific indicators. Examples are: a pre-planned PCC package; place of PCC delivery – i.e. hospital inpatient/outpatient, home, community care; consultation types, e.g. specialist levels, multidisciplinary team, distant electronic monitoring and follow-up etc. Quality indicators for reimbursements may be systematic use of PCC diagnostics such as PROMs in routine care and clinical decision making, family follow-up, time spent at home, and death at the preferred place. Importantly, symptom control is complex and appropriately trained multidisciplinary teams with a clear mission must be recognised as instrumental for success (see Figure 1).

Figure 1 shows the necessary joint actions by target institutions to improve integration of TCC and PCC as well as improving access to palliative care. These include international bodies such as WHO and EU, health care providers and educators at several levels, together with patients and families and their

**Figure 1:** The Patient Centred Care (PCC) integration ladder

Sources: Authors' own.

interest organisations. Universal access to palliative care must be ensured by legislative regulations and financial incentives. The voice of patients and families must always be acknowledged.

## Conclusion

A greater understanding about the influence of CDoHs on cancer care is needed by all parties, followed by explicit actions to address the imbalanced incentives in tumour-centred and palliative/supportive care. The time has come to join forces and develop a model with informed implementation strategies for integrated PCC and TCC to the benefits of patients, families and society.

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# THE ROLE OF GOVERNMENTS AND INTERNATIONAL AGENCIES IN ADDRESSING THE COMMERCIAL DETERMINANTS OF CANCER

By: Bettina Borisch and Wendy Yared

**Summary:** The role of governments and supra-national organisations is crucial when it comes to cancer prevention and control. They provide regulations that shape the activity of businesses on the national and global level. The Framework Convention on Tobacco Control is taken as an example of a global regulation that addresses the commercial determinants of health. Cancer is very high on the European political agenda, as such there are elements in the new Europe's Beating Cancer Plan which may positively encourage commercial drivers. There is a need for an effective system of checks and balances on the market forces which are present at all levels.

**Keywords:** FCTC, Cancer Prevention, European Code Against Cancer, Political Determinants, Commercial Determinants

## Introduction

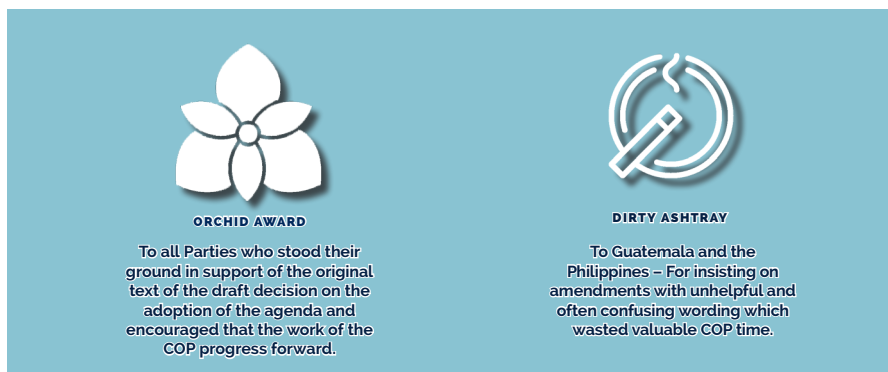
Cancer shares the characteristics of several chronic diseases, in such a way that they cover the whole pathway through the health and the social system. This implies that at all points of the pathway – from prevention and early detection to palliative care – the journey is subject to influencing factors, such as social and commercial determinants of health. Commercial determinants of health are private sector activities that affect people's health positively or negatively.<sup>1</sup> There are effective public health actions to respond to the potential challenges or negative effects of products which may pose a risk to health, which is the topic of this article.

In national and multilateral governance systems, these actions may be at different levels. From a potential cause of disease perspective, the respective action may focus on one or more parts of the disease pathway. Proven effective measures include raising the price (mainly by taxation), smoke free policies in public places, as well as restrictions on marketing possibilities of the tobacco industry. Less effective, but politically easier to introduce methods are mass media anti-smoking campaigns and curricula in schools. The value of these interventions in terms of effectiveness and feasibility is well researched<sup>2</sup> and may help with other industries as well.

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**Figure 1:** Governments are identified for good or bad behaviours by NGOs at global WHO tobacco control conference



Source: <sup>8</sup>

### Action at the prevention level is key – *The case of tobacco*

For the prevention part, Galea and Castro in their article in this issue point out that tobacco control is the “litmus test for the credibility of any program that purports to prevent cancer” and argue for the role of regulators at all levels. The positive example of such strong international leadership is the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC). The FCTC, adopted in 2005, clearly asks for structural and individual measures to prevent tobacco consumption.

“Commercial will in these industries to advance health may have been overestimated

The commercial interest of the tobacco industry has been put up against the health of populations. This international agreement helped governments to stand up firmly against the tobacco industry, as shown by the case of Uruguay.<sup>9</sup> The country very successfully implemented the

FCTC and is one of the global leaders in addressing tobacco industry interference. Both the FCTC and Uruguay show that important public health leadership is necessary. The momentum of the tobacco control programme in Uruguay is an excellent model of inspiration for other countries. It was not until 1999 that actual negotiations began, one year after the WHO Director General (1998–2003) Gro Harlem Brundtland, had made global tobacco control a priority for WHO.

On the other end of the spectrum is Switzerland where the FCTC is not yet ratified. The presence of the tobacco industry in the country is strong, both as part of the productive economy and as lobbyists in the political arena. The 2021 edition of the Global Tobacco Industry Interference Index ranked this country as the second highest with industry interference.<sup>10</sup>

One only needs to attend an FCTC Conference of the Parties (COP)\* <sup>5</sup> <sup>6</sup> to witness first-hand how the tobacco industry lobbies government representatives to vote in favour of industry objectives.<sup>7</sup> Anti-tobacco NGOs have created awards to demonstrate how stakeholders have participated in meetings – with the ‘Dirty Ashtray’ award to call out unhelpful contributions or the ‘Orchid Award’ for those who encourage anti-tobacco progress (see Figure 1).<sup>8</sup>

\* The Conference of the Parties (COP) is the governing body of the WHO FCTC and is comprised of all the Parties to the Convention, see <https://www.who.int/fctc/cop/governance/cop-sessions/en/>

During the last COP in 2018, the *Foundation for a Smoke Free World* funded by Philip Morris International organised an event in Geneva at the same time as the FCTC COP8 <sup>9</sup> to attract the media and governmental delegates away from the conference.<sup>10</sup>

### Responses at the European level to combat commercial determinants of cancer

The European Union’s (EU) efforts in cancer control date back more than three decades from the first Europe Against Cancer programme in the mid-1980s. It was during this era that the European Commission provided funding to WHO’s International Agency on Research for Cancer (IARC) to develop and update the European Code Against Cancer (ECAC), designed as a set of easy-to-understand messages by the general public on the primary and secondary prevention of cancer. The most recent 4th edition was published in 2014.<sup>11</sup> For each message, commercial determinants can be mapped. For example, the recommendations to limit red meat and alcohol, prompted renewed push back from these industries after the Code’s revision in 2014, via the media<sup>†</sup>.

In support of Europe’s Beating Cancer Plan <sup>12</sup> as a “key pillar of a strong European Health Union”, the European Commission stepped up its support on the promotion of the Code by including it in its funding envelopes for applicants as part of the EU4Health Programme and thus making it part of the system based on competition in which anyone can apply, since both NGOs and industry fit the eligibility criteria.

The Beating Cancer Plan now provides the basis for many of the EU4Health’s funding areas.<sup>13</sup> A system based on competition will inevitably include commercial competition throughout the whole field and among all stakeholders. Although the tobacco industry is not eligible, due to Article 5.3 of the FCTC, we can expect to see more interference from the for-profit sector. It is important to protect the public health and overall public interest

† See article in *The Local* from 27 October 2015. Available at: <https://www.thelocal.fr/20151027/i-survived-the-war-il-not-giving-up-saucisson/>

in future research projects, which will be funded within the Horizon Europe programme, based on strong support and recommendations of the Mission on Cancer.

Actions as part of the Plan's Flagship initiatives are reiterating or revamping past efforts by the European Commission to address areas such as alcohol consumption and unhealthy diets. The European Commission, in its efforts to guarantee transparency in advertising by companies, and to encourage multi-stakeholder collaboration, addressed at least two areas related to the ECAC with two multi-stakeholder networks, one on alcohol and one on diet and physical activity. By sharing activities as "commitments", all sides were able to see what others were doing to encourage healthy diets, such as removing junk food from school cafeteria vending machines. Both issues are laden with commercial interests, which had previously prevented key stakeholders from introducing stricter approaches. Evidence is mounting on alcohol as a causal agent or a contributor to many cancers (and other NCDs).<sup>14</sup> In terms of nutrition, we now have evidence from several EU Member States on how taxes on sugar or schemes on reducing salt in production processes were effective in terms of reducing intake of sugar and salt (e.g. Portugal and Lithuania, to name just two).

Commercial will in these industries to advance health may have been overestimated. NGOs were continuously deceived by the alcohol industry in the Alcohol and Health Forum established in 2007.<sup>15</sup> NGOs felt that the alcohol companies sat around the table with health NGOs committing words but not actions to reduce alcohol-related harm, resulting in NGOs walking out en-masse.<sup>16</sup> Without the NGOs, the European Commission had difficulty continuing to call it the Alcohol and Health Forum and all activities ceased. The Platform on Diet and Physical Activity and Health started in 2005, where health NGOs sat around the table with snacks, fast food, and sugar-sweetened beverage industries, but went dormant after 2018 and was officially discontinued in 2021.

Commercial drivers can also serve as necessary drivers for cancer control and prevention. The encouragement of commercial drivers is seen throughout Europe's Beating Cancer Plan. One of the main aims is to boost digitalisation and computerised tools. The Plan wants to boost funding for cloud computing, another incentive for tech. The plan includes Flagships that encourage Member States to extend HPV vaccination to both girls and boys and to develop new technology for cancer diagnostics.

In addition to the Beating Cancer Plan, the technology sectors are actively contributing to the proposal of a European Health Data Space (EHDS) to support the primary and secondary use of data. The eHealth Stakeholders Group, for example, has been given a mandate to provide input into the EHDS.<sup>17</sup> Because they are working alongside trade associations and health NGOs,<sup>17</sup> it is expected that their commercial incentives will be checked. On the other hand, because they have more resources, they may be determining and leading others in the directions to be taken.

### **New drugs and technologies: the promised solution?**

Other aspects of cancer control other than prevention are also subject to the interplay between economy and health. Cancer particularly attracts rapid development in terms of new drugs and technologies, as cancer is seen as the most lucrative part of health care. Due to the potential life-limiting nature of the disease and the despair of patients and their families, the willingness to pay – even out of pocket – is very high. In Europe, where cancer is predominantly covered by national and social health insurance schemes, more pressure by the commercial sector is put on 'motivating' decision makers to demand public funding for the 'new' and 'more efficient' treatments. This is very visible in the treatment part of cancer where new "promising" drugs can be put on the market with very high prices but with little or no evidence of success. Such companies often use patient and cancer control organisations to boost their products, by, for example, being a major 'contributor' both as a

financer and hence an influencer to the activities of the organisation, and/or by sponsoring events on a specific cancer that is related to a drug about to be launched. However, sometimes rewarding sales and commercially-driven incentives should be welcomed, such as for rare cancers, where incentives may be lacking for companies, and access can be especially complicated. Public authorities' response to the challenges described above could involve a mixed solution – e.g. strong and scientifically sound authoritative regulatory mechanisms, including consideration for health technology assessment, coupled with an enhanced public funding of research but independent of lobby influence.

“cancer is seen as the most lucrative part of health care”

Treatment, diagnostics and screening of cancer are also a big "market". Here the possibilities of "new" technologies are invoked on a regular basis. Some of the techniques are still at a research level, but they are already sold as a product to professionals and consumers at that stage. It has been shown that screening of certain cancers can reduce the cancer specific mortality (see the article by Hogarth on the commercial drivers of screening in this issue). This has to be done with a properly managed public health guided and research- and evidence-based program. The so-called "opportunistic" screenings that exist in all European countries, escape analysis, quality assurance and evaluation since no data are systematically collected. Even worse, selected populations (e.g. high-income, self-selected, more prevention aware) are 'studied' as if they had been selected according to strict epidemiological standards and serve as nominal 'proof' of effectiveness. With the more novel technologies, such as artificial intelligence, there is still much to sort out in the areas of ethics and regulations.



These areas must be addressed in a multisectoral manner, with input from clinicians, lawyers and even philosophers. Cancer control evolves where market forces are in place. Our economies are built on competition and assets. A free and insufficiently regulated market in cancer control will deepen the already existing inequities within and between countries. Health as a common public good has to be protected so that it is accessible to all citizens. In the quandary between conflicting forces the role of regulatory bodies and political leadership is key. It would be useful for an international norm setting body such as the WHO to come up with a framework (such as the FCTC), and the European Commission (such as the EU's Tobacco Products Directive), but in general, health is a Member State competence, and national political will is mandatory to implement cancer control strategies.

An example for a national regulatory body is NICE, the National Institute for Health and Care Excellence in the United Kingdom. This institution also evaluates the clinical benefit and financial cost of health and care measures in an independent manner. For the EU, the European Commission's Initiative on Breast Cancer (ECIBC) makes the case to offer health care providers and women clear guidance on screening and care. This is based on the latest scientific evidence available, according to a GRADE protocol and regularly updated. Enhanced activities extending to colorectal and cervical cancer are underway and will be supported by the EBCP.

### Action at the regulatory level – The case of sunbeds

Governments may not always be aware of the role they have in addressing commercial determinants, unlike in the area of tobacco control. In Europe, national governments have a role in regulating sunbeds ("tanning devices") at the European Commission level. Sunbeds are carcinogenic to humans and avoiding use is among the core messages in the European Code Against Cancer.<sup>18</sup> The European Commission further emphasised their risk in a 2016 scientific report concluding that "there is no safe limit for

exposure to UV radiation from sunbeds".<sup>19</sup> Addressing measures to prevent their use is also part of the Implementation Roadmap for Europe's Beating Cancer Plan.<sup>20</sup> One would therefore expect that the responsibility of regulating sunbeds falls under the health directorate (DG SANTE) of the European Commission. However, while this was the case years ago, it is currently with the Commission's DG GROW for internal market and industry, specifically under the Low Voltage Directive (LVD). Member States "authorities, standardisers, and **industry stakeholders**" make up the groups taking part in LVD Working Party meetings to agree on the harmonisation of laws and making available (or not available) devices in the market.<sup>21</sup>

Member States can in principle vote to remove sunbeds from national markets, but there are at least two barriers to this possibility. Firstly, due to the nature of LVD's mandate being concerned with health and safety only as related to the input or output voltage, there is no legislative mandate to remove sunbeds from countries. As long as sunbeds fall under the acceptable electrical limits, they are regarded as safe and its classification as a carcinogen does not come into consideration.<sup>22</sup> Secondly, governments can, and sometimes do, appoint trade or industry representatives to represent them at LVD meetings for their expertise on agenda items such as assessing electrical requirements for kitchen appliances and whirlpool baths to ensure they are safe to the consumer. This is logical, but certainly not for sunbeds which are intrinsically carcinogenic, and therefore no amount of regulation can make them safe. Either unwittingly or not, governments invite sunbed industry representatives to the discussions when sunbeds is an agenda item, who of course ignore this fact, deflecting the discussions to focus only on voltage requirements. Hence, the Association of European Cancer Leagues (ECL) and other skin cancer prevention organisations (EUROSKIN and EUROMELANOMA) have been lobbying Member States in the LVD working party for the sunbeds dossier to be moved back to DG SANTE to ensure that a proper discussion on regulating sunbeds – as a carcinogen – takes place.

The strength of such regulations and institutions is dependent on the respective political will. We can observe these political determinants of health at play very clearly during the ongoing COVID-19 pandemic. Society as a whole is subject to opposing forces and civil society is not exempt from it. So, as well as governments, civil society organisations have to be scrutinised too for any conflict of interest that may occur. Systems for checks and balances must be in place. The above-mentioned initiatives by the European Commission, with stakeholders from the private and non-profit sectors, can be seen as an example of a system with such checks and balances. Particularly as the health care sector – including preventing and treating cancer – represents a big part of countries public spending.

### Going forward, balancing health and the economy remains a priority

During the COVID-19 pandemic the discourse that protecting health is detrimental to the economy has been a commonly heard myth. In the strategies post-COVID this framing has to be opposed by different stakeholders including the voice of civil society, political leaders, academia as well as the private sector including the financing industry in addition to several others. It is important to make the case for a healthy population creating healthy economies. This needs a broad societal discussion and consensus. Cancer is one of the landmark cases to illustrate the argument. But as for tobacco, other fields such as Big Food, Big Alcohol and soon Big Tech call for joined and coordinated actions but, as we see from the European examples, effective collaboration will not be easy and will require will and determination.

Governmental and civil society action is needed, as well as the coordination of international bodies. But for there to be any successful and sustainable collaboration, the "Big Ones" must demonstrate that they are worthy of our trust. They have to do much better than they have, to convince all that they genuinely have an interest to advance health for all, and this commitment for a healthier world will not be overshadowed by their incentives for profits. The case

of cancer helps to push the agenda as it is prevalent, well researched and of personal concern to many.

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# ETHICAL QUESTIONS SURROUNDING THE COMMERCIAL DETERMINANTS OF HEALTH: **MOVING TOWARDS POLICIES THAT PROMOTE EQUITY, AUTONOMY AND WELLBEING**

By: Anya Plutynski

**Summary:** This article reflects on the key lessons emerging from this special issue of Eurohealth. There are a variety of both ethical and methodological concerns that authors have drawn attention to. They raise questions about how economic incentives are misaligned with promoting overall quality of life, can lead to compromises in quality of research and lower regulatory standards, misleading advertising of benefits, and rising costs, as well as disproportionately negative impact on underserved populations. To address these challenges, policies should set stricter regulatory standards, improve transparency, redirect economic incentives, improve medical education, and anticipate downstream impact in low-income countries. Such policies will promote greater autonomy, equity, and wellbeing.

**Keywords:** *Cancer, Commercial Determinants, Equity, Autonomy, Justice*

## Introduction

The previous articles in this special issue describe how the commercial and social determinants of health affect everything from public health recommendations regarding prevention and screening to tools and strategies for diagnosis, standards of care for treatment, and options available for palliative care. This article aims to put both the benefits and harms of these determinants into a

larger perspective, providing a normative foundation for the variety of suggestions for policy change offered by the authors. Additional suggestions will be offered for how to make more transparent the role of commercial interests in everything from basic science to clinical research, via reformed regulations that promote better health. There are many others who have drawn attention to the importance of greater transparency in communication about cancer risk. For further insights into

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how best to improve transparency, and resist misleading and over-hyped claims about causation and intervention, in both basic science, and clinical practice, see further references.<sup>1</sup>



economic  
incentives affect  
all areas of  
science

This article will discuss the main ethical considerations of the commercial and social determinants of health in the context of cancer (as defined by the introductory article in this issue) when one or more of the following conditions are met:

- a clear causal link with cancer, whether affecting our understanding of cancer, via shaping of basic science, or influencing cancer risk, diagnosis, treatment, or mortality,
- a defined commercial interest in the production and sale of products related to cancer outcomes (whether cancer incidence, mortality, diagnosis or treatment)
- a transnational ecosystem of producers, retailers, marketers, politicians, banks, trade associations, think tanks, scientists, and other entities devoted to the sale of commodities affecting cancer incidence, diagnosis or treatment.<sup>2</sup>

With regards to the matter of causal links with cancer, different regulatory agencies deploy different standards of evidence, so for the purposes of this article, I endorse Hill's (1965) argument for when we are warranted in judging a link to be causal, according to which, epidemiological evidence is better or worse, provided that the link exhibits greater strength, consistency, specificity, temporality, biological gradient, plausibility, coherence, experiment, and analogy.<sup>3–6</sup>

## Ethical Concerns

The increasing cost of cancer care globally is expected to be in the region of \$458 billion by 2030.<sup>7</sup> This striking amount raises ethical concerns regarding the economics of cancer prevention and care. There are four overlapping ethical concerns that reappear across the articles in this special issue, which will be addressed in turn:

- Concerns regarding quality of research and regulatory standards
- Economic incentives misaligned with promoting overall quality of life
- Misleading representation of public health and clinical information
- Rising costs and downstream impact on underserved populations, leading to concerns about equity in access

First, several articles raise concerns regarding quality of research and inadequate standards for approval of new drugs and treatments. Economic incentives affect all areas of science, from the direction and priorities of the basic sciences to the development of novel drugs or treatments. In many cases, this may slant research in particular directions, and may lead to lesser quality research. Rather than aiming at inquiry into measures that might, for instance, reduce overall incidence, or promote quality of life, focus is primarily on research that generates products that recoup investment quickly. For instance, there has of late been substantial investment in both basic and applied research directed at precision medicine. This has led to substantial investments in cancer genomics, for instance, with the attendant hope that such research will enable the development of targeted diagnostic tools and drugs. Such investment may eventuate in better outcomes, in the long run, but in the short term, some critics worry that this has led to lower quality research. Kaasa et al., authors of the article on palliative care in this special issue note that their clinical survey respondents repeatedly raised concerns about inflated estimates of benefit of novel drugs, little attention to side effects, and constant efforts at expanding indications for novel drugs.

Economic incentives promote the development of new drugs with ever expanding applications, which may lead to testing against weak comparators, and approvals based on modest effects in novel contexts. In the discussion of development of new screening technologies, diagnostic tools using molecular biomarkers, new precision therapies, or targeted drugs, there were concerns raised by all the authors about whether the measures of effectiveness were adequately validated. Surrogate measures of benefit, for instance, may or may not track outcomes that matter to patients, such as overall reduction in mortality and quality of life.<sup>7, 8</sup>

Second, several authors expressed concerns about how social factors and economic incentives shaped clinical care, advertising, and investments, in ways that do not promote overall health and wellbeing. In Kaasa, et al.'s discussion of palliative care, they note that there are strong incentives to focus on offering treatment as long as possible, rather than turning to palliative measures. Continuing to offer last ditch treatment options at the end stages of disease may well be profitable, but it comes at a very serious cost: reinforcing the false hope of patients at the very end stages of disease, leading to more suffering and less easeful death. Instead, they argue for more focus on palliative care, integrating "patient centred" care with what they characterise as "tumour centred care". Such shift in focus will promote greater quality of life at the end of life. They also argue for policies that promote economic reimbursement for end-of-life supportive care, and better education in the medical curriculum around palliative care. By and large, there seem to be insufficient economic incentives for developing palliative care, supportive care, early diagnosis and prevention. Likewise, also, Hogarth raises concerns about "commercial capture" of screening research and development, as well as growing market in direct-to-consumer advertising for novel diagnostic tests. Physician detailing and lobbying on behalf of industry to promote cancer screening research and technology development has led to an overselling of benefit of such tools and technologies,

and underappreciation of harms, such as fear and anxiety around false positives, or overdiagnoses.

In the context of public health, for instance, Galea and Castro document how the “tobacco playbook” includes tactics to stymie efforts at health policies that aim at reducing consumption of cancer-causing commercial products. For instance, industries threaten lawsuits, warn of costs to the economy, or threaten to eliminate funds for actions that go against their interests. Such industries also promote misleading research to downplay or misrepresent the negative health effects of their products. Economically depressed countries have some of the highest rates of smoking, due to a deliberate campaign on the part of tobacco companies to refocus advertising away from countries that have subjected these industries to heavy regulation. Less regulation of tobacco stimulates heavier investment on the side of the industry into advertising, which has led to steeply rising rates of cancer incidence and mortality in the developing world, particularly India, the Middle East, and China.

Third, and relatedly, many authors brought attention to concerns about the misleading nature of advertising around cancer risk and cancer treatments. They raised concerns over overselling of benefit of cancer drugs, as well as novel technologies – whether in service of diagnostics, imaging, pathology, surgery, radiation, or digital technologies. Medicines that add only a week or months to life are promoted as providing great benefit, and quality of life is not addressed adequately. Older drugs that may be just as effective tend to be underutilised. Moreover, these drugs may not be available, because their patents have expired, they disappear from the market despite their proven value. In addition, false hopes are fostered both in the marketing of new modes of detection, diagnosis and treatment. As Hogarth argues, potential benefits of screening may be oversold, and harms of screening – for instance, high rates of overdiagnosis and false positives – may be obscured by the introduction of commercial interests and capture of public bodies by such interests into this public health domain.

Likewise, as Sullivan et. al., point out, technological innovations are promoted, and research conducted without adequate consideration of clinical utility, potential cost in different communities, and variable impact. More attention needs to be devoted to the challenge of translating novel tools and technologies into the clinic, and funding should be directed at translational research, as well as upstream basic science. The commercial emphasis on technological and pharmaceutical novelty leads to myopia when it comes down to expanding access to care, and public sector work on how to implement these new tools.

“commercial emphasis on technological and pharmaceutical novelty leads to myopia”

Fourth, economic drivers shape the rising costs of care, which disproportionately affect the least well off. For instance, the relentless press for novel drugs and “technomania” in part has contributed to the rising costs of new drugs and screening technologies, which makes access to care yet more remote for many patients, particularly those in developing world. Commercial determinants shape overselling of novel (newly patented) modes of delivery of various opioids, for instance, leading to excessive costs of such drugs, when countries with limited resources might equally as well benefit from simple, generic versions of these same drugs.

In sum, there are matters of ethics and justice across the board, as illustrated in the accompanying articles in this special issue. The issues of justice have to do with respect for autonomy,

equity, and beneficence. They concern autonomy, insofar as fair and transparent communication of cancer-relevant information – whether upstream risk and preventive care, or downstream treatment – is essential for autonomous decision making; equity, insofar as equitable access to efficient and appropriate screening tools, therapies and palliative care, is essential to equitable health outcomes, and beneficence, insofar as governments have an interest in resisting commercial control of regulatory standards and health policies that may or not promote overall wellbeing.

## Policies

How are these concerns to be addressed? A variety of suggestions were offered, which involve interventions at the national level, as well as local issues, which, if implemented, would significantly improve respect for patients’ autonomous decision-making, equitable access to care, and overall quantity and quality of life. Five main suggestions stand out:

- Stricter regulatory standards
- Transparency both in advertising, and among stakeholders (carers, clinicians, patients, industry, policy makers)
- Regulatory tools to redirect economic incentives to improve wellbeing
- Improvements in medical education
- Policies that anticipate downstream impact in low-income countries

Arguably, policies across the board need to engage all relevant stakeholders if we are to improve overall population health and wellbeing. Such concerns should drive stricter regulatory standards, such as pre-registration of clinical trials, stricter criteria for validation of surrogate measures of benefit, better tracking and documentation of side-effects and harms of various interventions, as well as prohibition of any revolving door effects to do with industry and regulatory partners moving between the public and private sector. Ideally, changed incentives might limit the excesses of false advertising discussed in this special issue. More transparency in communication of the actual versus hoped for benefit of cancer

drugs is more respectful of patients and families, who often pin false hopes on oversold novelty.

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Regulatory tools could be used to incentivise investment in preventive measures, better palliative care, and more integrative care. Improved medical education of the roles of commercial interests in shaping cancer care might alleviate the tendencies toward

“technomania,” so that medical students have a better appreciation of both costs and benefits of novel treatment and technologies, as well as the importance of palliative and end-of-life care. Last but certainly not least, attention to the most underserved populations will require better pipelines for access to both standard drugs and the most effective new drugs and screening modalities. Future research might consider differential effects on vulnerable populations: such as ethnic minority groups, gender and sexually diverse populations.

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## Childhood cancer inequalities in the WHO European Region (2022)

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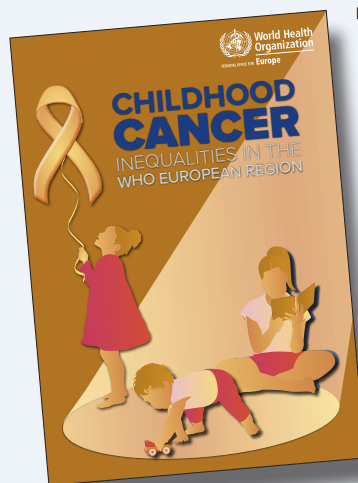
Childhood cancers include a wide range of rare cancers defined by the age group in which they occur. In recent years, significant progress has been made in improving survival rates and quality of treatment for children with cancer, but inequalities still exist across the WHO European Region.

In this report, the authors present the available evidence and information on childhood cancers within the WHO Region. In particular, they summarize literature in four main areas:

- the childhood cancer continuum;
- inequalities across countries;
- inequalities within countries; and
- childhood cancer as a driver of inequalities.

The authors argue for an increased focus on addressing inequalities in childhood cancer within the WHO Region and

make recommendations on the key steps that are likely to have the greatest impact in reducing inequalities. The report is aimed at decision-makers and politicians from all countries within the WHO Region looking to address existing inequalities in childhood cancer care through targeted activities.







**OBSERVATORY VENICE  
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# Implementing innovation: how do we make best practice work? 24–30 July 2022

Innovation in health care creates great potential to improve lives; but how much of that potential is realised in everyday practice depends on the successful implementation of biomedical, technological and organisational innovations. This sounds easy, but it is not – and it is a really big issue. Gaps in the implementation of good practice are both well-documented and significant, and they impact access to good quality care, its equitable distribution, and the efficient use of resources. They can be attributed to a range of different factors, from a lack of material and human resources to insufficient stakeholder engagement or political support. Understanding how to stimulate and implement fruitful innovation can help decision-makers drive the transformation of health systems towards achieving their goals.

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- the roles of different stakeholders in implementation, including patients, professionals, provider organisations, payers, and how policymakers can best support these processes;
- learning from good practice elsewhere, and the potential for collaboration between European health systems;

- techniques for bringing about constructive change, and models for supporting effective change processes, including processes of de-implementation; and
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This Summer School is aimed at high-level professionals working at Ministries of Health or Health authorities at the national, regional or local level, public or private payers, provider organisations, professional societies, patient organisations and others who are responsible for fostering and implementing innovations to transform health care provision.

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