Big Tobacco: Role Model or Pariah for the Pharmaceutical Industry?

Prof dr N. Freudenberg

This article was written by Nicholas Freudenberg for the Symposium of the Geneesmiddelenbulletin on June 30th 2016 in Leiden ‘Science and Economy’. It was also translated and published in the Symposium-issue and in the July-issue of the bulletin.

Nicholas Freudenberg is Distinguished Professor of Public Health at the City University of New York School of Public Health. E-mail: Nick.Freudenergh@sph.cuny.edu

Introduction

In the last two decades, the public health community has generally agreed that the tobacco industry has no role in setting health policy or sponsoring research on tobacco. The Framework Convention on Tobacco Control bans industry participation in policy deliberations on Tobacco, most major global public health organizations and national health departments have sharply limited their interactions with representatives of the tobacco industry, and many universities and some journals no longer accept or publish research supported by the tobacco industry.

However, no such agreement has been reached on the appropriate role for corporations and trade associations in other sectors such as pharmaceuticals, food and beverages, and alcohol. Some health and business analysts emphasize that the different roles that the products of the tobacco, medicines, food and alcohol industries play in patterns of health and disease make any judgements inappropriate and misguided, especially in the case of the drug industry. ‘Such comparisons (between the tobacco and pharmaceutical industries) are not just absurd, they are irresponsible as they contribute to patients not taking prescribed medicines that can clearly benefit them’, wrote one former drug industry executive.

Other health researchers make the case that while the products may differ, the practices of the tobacco industry that led public health officials and researchers to disassociate themselves from this sector (e.g., deception on health harms, aggressive marketing, and political interference with health regulations) are also followed by food and beverage, alcohol and pharmaceutical corporations. In this view, the tobacco industry has served more as a role model to emulate than a pariah to be avoided and the corporate playbook this industry created in the decades after World War II has guided Big Pharma, Big Food, and Big Alcohol in their interactions with governments, consumers, and health and regulatory agencies.

In this review, I examine the evidence for these two positions by comparing the business and political practices of tobacco industry and the pharmaceutical industry, two sectors that play very different roles in contributing to global patterns of health and disease. The goal of this comparison is to gain insights that can guide the development of appropriate government and corporate roles for protecting population health from harmful corporate practices.

Clearly, the products of the tobacco and pharmaceutical industries are different. The former produces and sells tobacco in various forms that are the world’s leading cause of premature death and preventable illnesses, associated with 100 million deaths in the 20th century and an estimated one billion deaths in this century if current smoking patterns continue. Pharmaceutical companies, on the other hand, produce essential medicines that save millions of lives each year and reduce the burden of suffering for tens or hundreds of millions. Both industries, however, follow practices such as a trend towards
market concentration\textsuperscript{12} and tax evasion\textsuperscript{13} that are no different than the practices of other transnational corporations.

Box 1. Business and Political Practices.

<table>
<thead>
<tr>
<th>Business Practices</th>
<th>Political Practices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practices that contribute to profitability, return on</td>
<td>Practices that create economic and political environments that allow companies to</td>
</tr>
<tr>
<td>investment and increased market share</td>
<td>advance their business goals and minimize threats to profitability</td>
</tr>
<tr>
<td>Product design</td>
<td>Lobbying</td>
</tr>
<tr>
<td>Marketing</td>
<td>Campaign contribution</td>
</tr>
<tr>
<td>Retail distribution</td>
<td>Sponsored scientific research</td>
</tr>
<tr>
<td>Pricing</td>
<td>Public relations and media advocacy</td>
</tr>
<tr>
<td>Philanthropy</td>
<td></td>
</tr>
</tbody>
</table>

The Practices of the Tobacco Industry

Acknowledging that their products are different does not, however, speak to the question of the similarity in their business and political practices. Box 1 defines these terms. To compare Big Tobacco and Big Pharma on this dimension requires a brief summary of the practices of the tobacco industry. Recently, several historians and public health researchers have analysed the records of the tobacco industry in the second half of the twentieth century\textsuperscript{14} \textsuperscript{15} Their analyses reveal some of the business and political strategies, summarized in Table 1, that the tobacco industry has used to ensure profitability, increase the market share of their companies and create a political environment that maximized their opportunities to pursue their financial goals.

Table 1. Business and Political Practices of the Tobacco Industry.\textsuperscript{11-13}
## Business Practices

<table>
<thead>
<tr>
<th>Practices</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product design</td>
<td>Redesign products to give appearance of healthfulness (e.g., filters, low tars) or to appeal to new populations (e.g., menthol for African Americans, slims for women)</td>
</tr>
<tr>
<td>Marketing</td>
<td>Use targeted marketing to vulnerable populations (e.g., cartoon characters for youth), misleading health claims, use and celebrities as marketing agents</td>
</tr>
<tr>
<td>Retail distribution</td>
<td>Expand retail opportunities to make product ubiquitous by placing tobacco products in food, drug and convenience stores and vending machines everywhere</td>
</tr>
<tr>
<td>Pricing</td>
<td>Offer volume discounts, create luxury and bargain brands, oppose taxation that increases prices</td>
</tr>
<tr>
<td>Trade policy</td>
<td>Advance trade treaties that reduce national government power to implement Framework Convention or to challenge intellectual property rights to branded images</td>
</tr>
</tbody>
</table>

## Political Practices

<table>
<thead>
<tr>
<th>Practices</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lobbying</td>
<td>Urge elected bodies to reject taxes, smoking bans or stronger regulation of tobacco marketing</td>
</tr>
<tr>
<td>Campaign contributions</td>
<td>Contribute to campaigns of politicians who oppose public health controls of tobacco</td>
</tr>
<tr>
<td>Public relations</td>
<td>Advocate individual choice and responsibility, unfettered free trade and value of self-regulation and voluntary public partnerships</td>
</tr>
<tr>
<td>Philanthropy</td>
<td>Contribute to popular causes to enhance credibility and enlist grantees in supporting (or not opposing) industry in public debates</td>
</tr>
<tr>
<td>Sponsored scientific research</td>
<td>Sponsor research that obfuscates harm from products, fund researchers to produce negative findings on harm from tobacco, challenge research methods that establish harm, hire industry-friendly writers to ghost write scientific articles, mask sponsorship of scientific research</td>
</tr>
</tbody>
</table>

In her 2006 decision in the United States vs. Philip Morris, Judge Gladys Kessler summarized the legal case brought by the U.S. Department of Justice against the several major tobacco corporations for fraudulent and unlawful conduct and reimbursement of tobacco-related medical expenses. Her findings are worth quoting at length for their sweeping conclusions:
‘[This case] is about an industry, and in particular these Defendants, that survives, and profits, from selling a highly addictive product which causes diseases that lead to a staggering number of deaths per year, an immeasurable amount of human suffering and economic loss, and a profound burden on our national health care system. Defendants have known many of these facts for at least 50 years or more. Despite that knowledge, they have consistently, repeatedly and with enormous skill and sophistication, denied these facts to the public, the Government, and to the public health community… Defendants have marketed and sold their lethal products with zeal, with deception, with a single-minded focus on their financial success, and without regard for the human tragedy or social costs that success exacted… Over the course of more than 50 years, Defendants lied, misrepresented and deceived the American public, including smokers and the young people they avidly sought as ‘replacement’ smokers about the devastating health effects of smoking and environmental tobacco smoke… The evidence in this case clearly establishes that Defendants have not ceased engaging in unlawful activity… For example, most Defendants continue to fraudulently deny the adverse health effects of second-hand smoke which they recognized internally; all Defendants continue to market “low tar” cigarettes to consumers seeking to reduce their health risks or quit… Defendants continue to fraudulently deny that they manipulate the nicotine delivery of their cigarettes in order to create and sustain addiction; some Defendants continue to deny that they market to youth in publications with significant youth readership and with imagery that targets youth; and some Defendants continue to suppress and conceal information which might undermine their public or litigation position… Their continuing conduct misleads consumers in order to maximize Defendants’ revenues by recruiting new smokers (the majority of whom are under the age of 18), preventing current smokers from quitting, and thereby sustaining the industry.’ 16

The Practices of the Pharmaceutical Industry

A growing body of evidence shows common pharmaceutical industry practices that resemble those pursued by tobacco corporations, as shown in Table 2. Further research is needed to document the prevalence, scope, and specific health consequences of these practices, most of which are legal.

However, if drug corporations claim that their commitment to advancing the well-being of humanity entitles them to be judged by different standards than those used for other businesses, then they have to be judged by these higher standards. If, on the other hand, drug makers assert they are just another business and have the same rights to pursue profit maximization strategies as any other business, then they cannot claim exemption from regulatory oversight.

Table 2. Selected Examples of Pharmaceutical Industry Practices that Harm Health.
<table>
<thead>
<tr>
<th>Practice</th>
<th>Consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product design</strong></td>
<td></td>
</tr>
<tr>
<td>Inadequate premarket testing</td>
<td>Drugs with common or dangerous side effects are released to market. Example: <em>Thalidomide</em>, <em>rofecoxib</em>&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Inadequate post-marketing surveillance</td>
<td>After release, inadequate surveillance fails to detect serious side effects before they harm health. Examples: <em>Cerivastatin</em>, <em>rofecoxib</em>&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Production of sub-standard drugs</td>
<td>Inadequate quality control or fraudulent practices lead to production of drugs that are unsafe or ineffective. Examples: dispensing of antimalarials and antibiotics with less than minimum of active pharmacological ingredients&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Marketing</strong></td>
<td></td>
</tr>
<tr>
<td>False or misleading advertising</td>
<td>Companies claim effectiveness without adequate evidence or make broader health claims than justified. Example: Genentech Inc. and OSI Pharmaceuticals LLC agree pay $67 million to resolve False Claims Act allegations brought by US Department of Justice that they made misleading statements about the effectiveness of the drug Tarceva® to treat non-small cell lung cancer&lt;sup&gt;d&lt;/sup&gt;</td>
</tr>
<tr>
<td>Aggressive marketing</td>
<td>Companies inundate physicians and other providers and consumers with ads for their products. Example: study finds that drugs that pharmaceutical companies marketed most aggressively to physicians and patients tended to offer less benefits and more harm to patients&lt;sup&gt;e&lt;/sup&gt;</td>
</tr>
<tr>
<td>Direct-to-consumer-marketing</td>
<td>Companies by-pass physicians to advertise directly to consumers, putting pressure of providers to prescribe unneeded or potentially dangerous products. Example: One study found that 82% of direct-to-consumer ads made some factual claims and rational arguments for use of the advertised drug; however, only 26% of the ads described risk factors or causes of the condition, and only 25% mentioned prevalence&lt;sup&gt;f&lt;/sup&gt;</td>
</tr>
<tr>
<td>Pharmaceutical representatives pay or otherwise induce physicians to prescribe products</td>
<td>Drug companies hire marketing representatives who aggressively promote products and offer incentives to providers to prescribe more. Example: Investigation of prescribing habits of US physicians found that highest prescribers received substantial payments from drug makers&lt;sup&gt;g&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Retail distribution</strong></td>
<td></td>
</tr>
<tr>
<td>Outlet density</td>
<td>Retail chains make over-the-counter and prescription drugs available everywhere, especially in urban areas, leading to higher levels of use, including possible unnecessary or unsafe use&lt;sup&gt;h&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Pricing</strong></td>
<td></td>
</tr>
<tr>
<td>Pricing essential medicines out of reach of those who need</td>
<td>Drug companies charge high prices or increase prices rapidly, contributing to skipped doses, inadequate treatments, development of resistance; in many middle and low income countries, substantial proportions of population lack access to essential medicines&lt;sup&gt;i&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
</tr>
<tr>
<td>Market consolidation</td>
<td>Drug companies merge or acquire other firms, reducing price and quality competition and increasing political influence with regulators and trade groups. Example: Several recent mega-mergers have led to reductions in spending on research and development&lt;sup&gt;j&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Political Practices</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Sponsored Research</strong></td>
<td></td>
</tr>
<tr>
<td>Commissioning research and ghost written scientific articles</td>
<td>Drug companies hire writers to ghost write scientific articles to specification, then list genuine researcher as author. Example: drug companies hired ghost writers to describe conjugated medroxyprogesterone acetate and rofecoxib, drugs subsequently recalled after known safety hazards were not disclosed&lt;sup&gt;k&lt;/sup&gt;</td>
</tr>
<tr>
<td>Withholding data from regulatory agencies</td>
<td>Drug companies fail to disclose or disclose only partially data documenting lack of safety or effectiveness. Example: GlaxoSmithKline withholds data on SSRI use in children&lt;sup&gt;l&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
Trade policy and intellectual property rights

Drug companies use trade treaties or national laws to extend patent protection, limit use of generics or oppose compulsory licensing of essential medicines. Example: Proposed Trans Pacific Partnership agreement extends patent protection reducing access to essential medicines.

Lobbying

Drug companies lobby legislators and government agencies to pass laws and enact or enforce regulations that benefit industry at expense of public health. Example: Pharmaceutical Manufacturing and Research Association successfully lobbies to eliminate measures to cut prices of drugs from Affordable Care Act.

Campaign contributions

Drug companies and trade associations contribute to candidates they expect to enact laws or policies that favor industry at expense of public health. Example: Between 1990 and 2008, drug companies contributed $108 million to U.S. political parties.

Public relations

Drug companies influence media coverage and political discussion to favor policies that protect profits. Example: Drug companies hire outside experts to promote their products to the media, sometimes failing to disclose sponsorship.

Philanthropy

Drug companies support charitable causes that enhance their credibility, co-opts critics, or frame issues to advance their business interests. Example: Drug makers contribute to patient groups to advocate for wider access to their products.

Sponsored scientific research

Drug companies sponsor scientific research that casts their products in a favorable light or obfuscates real or potential harms. Example: Pfizer testing of antibiotic Trovan® in Nigeria without obtaining informed consent.

Taxes

Companies buy overseas affiliates or place money in offshore tax havens, depriving governments of needed tax revenues. Example: Several transnational drug companies merge with small overseas companies to avoid US taxes.

A review of Table 2 and the sources from which it was extracted suggests that transnational drug companies regularly engage in activities that harm public health. While the data to quantify this impact have not been synthesized, a few estimates suggest the magnitude. A 2008 UN report estimated that more than 2 billion people lack sufficient access to essential medicines. While some problems originate in people lacking access to needed drugs, others stem from getting too many drugs or the wrong kind. A recent report found that ‘medical errors’ in hospitals and other health-care facilities may be the third-leading cause of death in the United States, claiming 251,000 lives every year. While medical errors have multiple causes, inappropriate utilization of medicines is a major contributor. A review of substandard drugs concluded that poor quality and fraudulently manufactured drugs are ‘widespread and represent a threat to health. Drug companies have been found guilty of, among other charges, promoting drugs for unapproved uses, inadequately monitoring patient safety, withholding evidence that documented harms from their products from regulators and the public, and paying competitors to keep less expensive versions of drugs off the market.

More broadly, estimates suggest that globally the majority of drugs are prescribed, dispensed or sold inappropriately and that about half of all patients fail to take them as directed. Drug industry practices that contribute to these dismal statistics include aggressive marketing of inadequately tested or unsafe drugs, physician education programs that emphasize industry profits than patient health, and inadequate consumer education. Moreover, like the tobacco industry, the products and production processes of the pharmaceutical industry can also harm the human and natural environment. Widespread promotion and use of antibiotics has contributed to human and animal drug resistance complicating the control of established and emerging infectious diseases. Overuse and improper disposal of pharmaceuticals has contaminated waterways and various ecosystems, jeopardizing humans and wildlife. Of course many other institutions and individuals play a role in these harmful practices, including pharmacists, physicians, professional organizations, hospitals, governments, and patients themselves. While each of these should contribute to devising solutions, none has more resources or more centralized control of its practices than the pharmaceutical industry.
Like the tobacco industry, the pharmaceutical industry acts aggressively to influence public policies that affect its bottom line. For example, between 1989 and 2012, the Pharmaceutical Research and Manufacturers of America (PhRMA), the trade association of drug companies, spent $225 million on lobbying to ensure that health care reforms in the United States did not threaten profitability, even if that meant making essential medicines more expensive for many vulnerable Americans. Similarly, national and transnational drug companies and their trade associations used their influence at the secretive negotiations for global trade treaties to enshrine intellectual property rights that protected profits at the cost of access to essential drugs.

In an analysis of the lobbying intensity of various industries, the business research group IBISWorld compared how much various sectors invested in lobbying. High-intensity industries were defined as those with a lobbying share that is at least four times greater than their share of total value added to the economy. Only three industries met this criterion: defence, pharmaceuticals and health products, and tobacco. The common characteristics of these sectors were identified as high regulatory exposure, dependence on government spending and market share concentration. Like the tobacco industry, the pharma sector uses its formidable political and financial resources to seek to ensure continuing profitability by spending resources to control the political environment in which it operates.

From the public’s perspective, few Americans rate either the pharmaceutical or the tobacco industry favourably. In a 2016 Harris Poll of a representative sample of United States adults, only 33% of the respondents thought the pharmaceutical industry had a good reputation and 16% thought the tobacco industry had a good reputation, the two lowest ranked of the business sectors included in the survey.

Summary and Conclusions

The tobacco industry prospered in the 20th century because it developed methods of producing, marketing, pricing and distributing cigarettes around the world, creating a growing customer base that ensured growing profits. It also prospered by investing in public relations, scientific, philanthropic and political infrastructures that could be used to advance its business goals.

In the last few decades, the global health community has launched a determined offensive against the tobacco industry. Through local, national and global action, it has limited the power of the tobacco industry to operate without public oversight, contributed to reductions in tobacco use in many parts of the world, and in many domains removed tobacco industry representatives from policy deliberations. Tobacco remains the leading cause of premature death and preventable illness but today it is possible to imagine a world where the burden of illness imposed by tobacco can shrink rather than grow.

In the last 100 years, through technological innovation, aggressive marketing and growing political influence, the pharmaceutical industry has become a leading global industry. In recent decades, the use of pharmaceuticals has grown dramatically, in part as a result of a growing global population, population aging and new discoveries. Some part of the growth can be explained by the industry’s success in bringing more effective and useful medicines to more people.

Another reason for the growth of the drug industry has been the use of the practices shown in Table 2. While all tobacco industry profits come from products that damage health, not every drug industry practice or products benefits health. In fact, as numerous analysts have shown, promoting non-rational, non-essential, and ineffective medicines may be as or more profitable than promoting only rational and essential use.

From a public health perspective, the key question for the drug industry is what policies will promote rational and effective use of essential medicines and what policies will discourage use of ineffective, harmful or unnecessary drugs. For this latter question, it seems obvious that the lessons from controlling the tobacco industry may prove relevant. Some questions that warrant empirical investigation include:

1. How can taxes on drug producers, prescribers, dispensers and users discourage inappropriate and unsafe use of medications? In the case of tobacco and alcohol and, more recently unhealthy foods, taxes have been used as an incentive for healthier practices and a penalty for harmful ones.
2. How can public policies on marketing, both to prescribers and consumers, limit use of deceptive or manipulative
advertising without unduly restraining commercial speech or doctor-patient-pharmacist relationships? New approaches to limiting tobacco advertisements, food marketing to children, and direct-to-consumer drug advertisements warrant further investigation.\textsuperscript{35-37}

3. What policies or strategies might discourage drug makers from externalizing the costs of ineffective, inadequately tested or harmful products to the government or consumers? Legal action against the tobacco industry helped to return the costs of harm to the industry rather than tax payers or governments.\textsuperscript{38} While the pharmaceutical industry seeks protection from such lawsuits, might performance-based regulation provide additional incentives for reducing harmful practices?\textsuperscript{39}

4. What are appropriate limits for drug industry involvement in setting drug policies? What disclosure requirements for political activities and contributions would limit inappropriate drug industry involvement in public policy? The Framework Convention on Tobacco Control bans any tobacco industry involvement in setting public health policy. Some corporate reformers are proposing that all corporations disclose all political contributions and avoid participating in policy decisions that benefit their company or industry.

5. What role should the drug industry play in sponsoring scientific research? Under what circumstances should universities accept industry funding for drug research? Many universities have decided to reject any funding from the tobacco industry. Extending this principle to the pharmaceutical industry could jeopardize the financial viability of some medical research institutions but stricter rules might limit conflicts of interest and restore credibility to both universities and drug makers.

By studying the practices of the pharmaceutical industry in some of the ways that tobacco researchers have studied that industry, it may be possible to provide the evidence that can guide public policies that maximize the benefits of modern medicines while minimizing their harms. Only governments, not markets, have the mandate, resources and authority to ensure that the good that medicines offer outweigh the harms they impose. Absent intervention, it appears likely that the continued market-driven growth of the pharmaceutical industry and its growing political powers will contribute to more adverse health effects and increasing inequalities in access to essential medicines. By learning the appropriate lessons from the various efforts to reduce the harmful practices of the tobacco industry, is it possible to imagine a world in which the burden of illness and environmental damage imposed by the drug industry will shrink rather than grow?

Reference list


5. Smith R, Gøtzsche PC, Groves T. Should journals stop publishing research funded by the drug industry? BMJ 2014; 348 : g171


17. The right to health-Note by the Secretary-General. http://www.who.int/medicines/areas/human_rights/A63_263.pdf

Reference list 2.


Authors

- Prof Dr N. Freudenberg