Money Versus Medicine

An interview with Alain Braillon.

To those who practice medicine, the private market has always been a double-edged sword. On the one hand, pharmaceutical companies develop the medications and devices that practitioners use to enhance patients' health and save lives. Other for-profit companies manufacture the exercise equipment, nutritional supplements, and healthy food choices that can often help consumers avoid getting sick in the first place.

But on the other hand, those same pharmaceutical companies periodically release defective medications and products that either do not work or exhibit harmful—in some cases lethal—side effects. While the wares sold for profit by other firms are frequently far from beneficial to consumers' health: For instance, tobacco products, fast foods, and household goods laced with toxic chemicals all contribute to public health problems. Companies that are unscrupulous expend great efforts to downplay or deny the defects or health dangers associated with their products, and to persuade government regulatory agencies to lower their guard. The twentieth century saw many examples of such civic irresponsibility in corporate behavior.

The twenty-first century's business climate appears to be even more problematic, according to French physician and whistle-blower Alain Braillon. Dr. Braillon served Amiens University Hospital as both a senior consultant in public health and as a regional advisor for quality of care from 2004 until September 2010, when he was "sacked" by the Amiens regional board. The National Management Center (France's national department of health) heard Braillon's appeal and, even though 70% of the health officials in the district voted against Braillon's dismissal, the national center nonetheless upheld the regional board's decision and, in an unusual departure from protocol, rendered their verdict without allowing Braillon to be present to defend himself.

Braillon is certain that his abrupt end to his career had much to do with his outspoken calls to curtail tobacco and alcohol advertising, and his strong views on several other prominent health topics: He urges mandatory hepatitis vaccinations and was one of the strongest voices for a French ban on benfluorex, a drug that the United States and several other countries had already outlawed due to its proven links to heart valve problems. France only followed through with its own ban in 2009.

Not coincidentally, according to Braillon, the French tobacconists' union sued Gérard Dubois (an Amiens University public health professor and Braillon's own one-time boss), for libel in 2010 following Dubois's statement in a televised interview that tobacco use had killed two persons for every tobacconist in France. The union did so in spite of scientific evidence that strongly supported Dubois's claim.

Braillon alleges that the alcohol, tobacco, and pharmaceutical industries have all exerted great pressure on lawmakers in France and elsewhere to let them pile up profits with impunity and to silence critics in the medical community. He further asserts that they aggressively pursue unsavory quid pro quo arrangements with doctors, inundating them and their patients with advertising and sponsoring research studies specifically to encourage the use of their brand-name medications. As a result, even conscientious doctors are hard-

pressed to distinguish reliable new products and drugs from spurious, under-tested, and potentially harmful ones.

Braillon argues that unless consumers and honest physicians organize to counter the influence of industry lobbying, the power of unethical business interests to exert undue influence over law makers and doctors and endanger public health will only expand. He discussed his concerns with Rick Docksai, *World Future Review* assistant editor.

World Future Review: I had believed that the tobacco industries no longer held much credibility. The percentages of adults who smoke has been declining for many years, and almost everybody understands now that smoking heightens your risk of cancer and other health problems. But clearly, your experience proves otherwise. What power do tobacco industries still have? How are they still able to impose their will on public policy-making, after everything that we now know about the dangers of tobacco?

Alain Braillon: Let's call a spade a spade! There is a real clash of discourses between the language we use and the language we should be using. Language, like the media, both shapes and reflects social values. Accordingly, inadequate language reflects inadequate involvement to face the challenges. One out of two smokers will die from smoking-related diseases. Moreover, what is sold on the market is not tobacco but a mixture of additives. For instance, ammonia is added to increase the alkalinity of smoke and increase the amount of nicotine in the free form rather than in the bound form of nicotine salts. This "ammonia technology" or "crack nicotine" was essential to the "soul" of Marlboro. So I use different terms such as "death industry" and "TOX-bacco."

Despite the fact that one out of two people addicted to TOX-bacco died from related diseases, the number of people addicted to TOX-bacco continues to rise! The death industry is continuously recruiting, targeting society's most vulnerable members, the youngest! The epidemic is spreading as a wildfire in the developing countries while it is only partially controlled in developed countries. In the United States, the prevalence of smoking only declined from 20.9% in 2005 to 19.3% in 2010, far from meeting the Healthy People 2010 objective to reduce cigarette smoking among adults to less than 12%.

[**Editor's Note:** Healthy People is an ongoing U.S. government objective that sets multiple public-health goals and 10-year spans for meeting them. Healthy People 2010 ran from 2000 until 2010, and was succeeded by Healthy People 2020. You can read more about Healthy People and the U.S. government agencies behind it at: www.healthypeople.gov.]

Worldwide, over five million people die each year from TOX-bacco use and the expected figure could be more than eight million by 2030. Philip Morris International embodies the power of this industry. This company alone has 77,000 employees, generates $27 billion a year in revenue, and boasts $107 billion of capitalization. This giant just filed a suit in the World Bank's International Centre for Settlement of Investment to dispute against courageous little Uruguay (Gross Domestic Product of $44 billion) which became the first country in the world to require that 80% of a cigarette package be devoted to health warnings. In June 2011, Phillip Morris International also disputed Australia's plain cigarette packaging anti-smoking legislation.

It is the same in the United States. The Food and Drug Administration released in June 2011 nine new warnings to go into effect in September 2012. District Judge Richard Leon sided with tobacco companies and granted a temporary injunc-

tion, saying they would likely prevail in their lawsuit challenging the requirement as unconstitutional because it compels speech in violation of the First Amendment. The Obama administration has appealed the judge's ruling that blocked requirements for tobacco companies to display graphic images on cigarette packages.

Health warnings on cigarette pack are one of the most powerful tools for tobacco control. But their relative prominence reflects a complex balance between government's concerns about their citizens' health and the influence of the tobacco lobby.

France was only the 39th country in the world to enforce the Framework Convention on Tobacco Control (the world's first global public health treaty which was negotiated under the auspices of the World Health Organization) recommendation about pictures on packages in 2011. The French government allowed the death industry an unbelievable two years for discussions plus a one-year grace period for using up stocks. Last but not least, the required size is only 30% of the front or 40% of the back. Philip Morris has not disputed France's decision!

France has become an exception among rich countries by flying in the face of evidence-based public policy. There is also long-standing evidence of the effectiveness of higher tobacco prices in reducing tobacco consumption. In developed countries, roughly a 10% rise in price decreases sales by 4%. In 2004, Jean Pierre Raffarin, Jacques Chirac's Prime minister, announced a freeze on tobacco taxes for four years—"a good compromise," according to the president of the Tobacconists Union. On May 30, 2011, Xavier Bertand, [French President Nicolas] Sarkozy's minister of health, announced that he will maintain the freeze, despite France having seen a 2% increase in smoking prevalence during the past five years, which is an exception among rich countries.

In France, the turnover of the tobacco industry has shown a 3% rise from 2008 to 2009, despite the global economic crisis. There are evidences that the French government is not far from being regarded as breaching Article 5.3 of the Framework Convention on Tobacco Control, which requires protecting public health policies from the tobacco industry influence.

But let's come back to the United States. There is an alarming lack of decline in TOX-bacco use. Local governments are responsible, but most neglect the issue. California is one of the few exceptions, with a 13% prevalence of smoking.

In 2009, President Obama signed legislation giving the Food and Drug Administration the authority to regulate the marketing and manufacturing of tobacco products. In September of that year, the agency ended the sale of flavored cigarettes—chocolate, vanilla, strawberry, etc.—which had aimed to lure children and women into smoking. This looks fine, but again it is another example of a flawed policy: The agency has not yet banned menthol cigarettes, the most used!

This tricky additive is the worst. Menthol was added to cigarettes to reach new consumers—e.g., women, who perceive the minty aroma of menthol cigarettes to be more socially acceptable than non-menthol cigarettes. Menthol also led to an increase in smoking among teens, African Americans, and those with low incomes. Lastly, menthol smokers are less successful at quitting. Surprisingly, in March 2011, the Food and Drug Administration's (FDA's) Tobacco Products Scientific Advisory Committee issued a report that failed to recommend a ban on menthol cigarettes. No one can understand why. The FDA said its decision was to be expected in fall of 2011.

Is the term "industry" appropriate? TOX-bacco dealers also fraudulently undermined and discredited the scientific consensus that passive

smoking causes diseases. On September 22, 1999, the U.S. Department of Justice filed a racketeering lawsuit against Philip Morris and others. Judge Kessler found that they had: (a) conspired to minimize, distort and confuse the public about the health hazards of smoking; and (b) publicly denied, while internally acknowledging, that secondhand smoke was harmful to nonsmokers, and destroyed documents relevant to litigation.

The ruling found that the defendants undertook joint efforts to undermine and discredit the scientific consensus that passive smoking causes disease, notably by controlling research findings via paid consultants. The ruling also concluded that defendants still continued to fraudulently deny the health effects of passive smoking. On May 22, 2009, a three-judge panel of the Washington, D.C., U.S. Court of Appeals unanimously upheld the 2006 Lower Court's ruling.

In 2000, the European Union filed a civil suit in New York under the Racketeer Influenced and Corrupt Organizations Act (RICO) against Philip Morris, R. J. Reynolds Nabisco and Japan Tobacco. All ended up in July 2004 with an agreement (Memorandum of Understanding, an unenforceable, non-binding agreement) between Phillip Morris and the EU. Phillip Morris undertook to pay $1.25 billion to compensate and close the issue of the damage done. It looked like almost pocket change. In Canada, many lawsuits were successful, and a wholly owned subsidiary of R.J. Reynolds Tobacco Company pled guilty to charges related to its involvement in smuggling cigarettes from the United States into Canada.

An estimated 446,000 Americans die each year from smoking-related diseases. That's the equivalent of two full Airbus A-380s crashing every week day plus three crashing every Saturday and Sunday). TOX-bacco costs the health care system $193 billion every year.

WFR: It's becoming common, so I am told, for physicians to have excessively strong ties to certain pharmaceutical companies and to publish articles touting those companies' products without disclosing their ties. It's understandable why this would present a major conflict of interest. But articles are peer-reviewed, after all. Why isn't the peer-review process sufficient to screen out questionable research? How do the industry-influenced doctors elude the peer review process and thereby disseminate their false findings or inadequately screened medical products to an unknowing public?

Braillon: Drug companies have long kept secret details of the payments they make to doctors and others for marketing their drugs. Pharmaceutical companies spend more on marketing than on research. President Obama signed the Physician Payment Sunshine Act, which requires pharmaceutical companies and other medical industries to report all direct payments or gifts over $10 that are made to physicians.

In an August 2011 article that was published on the Web site of Doctors for America, Maggie Kozel wrote: "Physicians have always had a complex relationship with the health care industries." [**Editor's note:** Doctors for America is a U.S.-based association of physicians and medical students working to make U.S. medical care more accessible, affordable, and effective. Maggie Kozel is a retired physician who teaches medicine and independently writes about health-care issues. You can read Kozel's statement at: http://www.drsforamerica.org/blog/the-sunshine-provision-raising-awareness-of-marketing-in-the-health-care-industry#.Tu_TJXrMfGg]

Again there is a real clash of discourses between the language we use in and the language we should be using. "Complex" means "very lucrative." If you want to know if your health pro-

fessional received drug company money, look at: http://projects.propublica.org/docdollars. And do not forget that conflict disclosed does not mean conflict resolved!

Editing is about money, and profits are easier to make from online publication. Research is about publishing. Everyone knows "publish or perish." The peer review process is a cheap process that cannot regulate this system. The editor does not pay the reviewer for his or her time and energy. The reviewer has only access to the manuscript and not to the raw data. Accordingly, the result is an enduring and ever-growing avalanche of low-quality research.

This has been well known for a long time. Drummond Rennie, deputy editor of the *Journal of the American Medical Association,* once said, "If peer review was a drug it would never be allowed onto the market." The *Journal* published a systematic review in 2002 that concluded that "Editorial peer review, although widely used, is largely untested and its effects are uncertain."

The nation's largest accounting firms, along with numerous watchdogs and regulators, all failed to catch the multibillion-dollar Madoff investment scam. Peer reviewers are just poor volunteers. Peer review is the weakest system that you can imagine.

WFR: Generally speaking, to what degree might the medical/corporate conflicts of interest that you describe increase overall health-care costs—for example by doctors encouraging costly and inefficient tests and treatments?

Braillon: Conflicts of interest do escalate increases in overall health-care costs. Indeed "Pill them, and bill them" may seem to be the new credo. This is true for both curative and preventive medicine.

The New York Times revealed that an Abbott executive wrote an e-mail celebrating a day in August 2008—"the biggest day he remembered hearing about." On that single day, Dr. Mark Midei inserted 30 Abbott cardiac stents. Two days later, an Abbott sales representative spent more than $2,000 on a barbecue dinner at Midei's home. A fortune is spent on procedures that people don't need and that may only harm them. Despite proper assessment, dilating and stenting of various arteries (including renal and carotid) has spread like wildfire since the 1980s. Patients had to wait until recently to learn that most of these vascular procedures provide no benefit over drug treatments and may cause serious complications.

Among patients receiving implantable cardioverter-defibrillators, more than one out of five do not meet evidence-based criteria for implantation, according to a study published in 2011 by Al-Khatib in the *Journal of the American Medical Association.*

For preventive medicine, the situation can be even worse, as evidenced by the screening for prostate cancer. Richard J. Ablin recently wrote:

> I never dreamed that my discovery four decades ago would lead to such a profit-driven public health disaster. The medical community must confront reality and stop the inappropriate use of PSA screening (prostate-specific antigen screening; a standard test for diagnosing prostate cancer). Doing so would save billions of dollars and rescue millions of men from unnecessary, debilitating treatments.

Also in the *New York Times,* Gardiner Harris provided a clear summary: "From 1986 through 2005, one million men received surgery, radiation therapy, or both who would not have been treated without a PSA test, according to the task force

[U.S. Preventive Services Task Force]. Among them, at least 5,000 died soon after surgery and 10,000 to 70,000 suffered serious complications. Half had persistent blood in their semen, and 200,000 to 300,000 suffered impotence, incontinence or both."

In 2010, Michael J. Barry wrote a piece in the *Archives of Internal Medicine* about the options for treatment of clinically localized prostate cancer. The title is also the bottom line: "The prostate cancer treatment bazaar."

In an ideal world every doctor would only practice evidenced-based medicine. Sadly, we are still far from the ideal. Too many doctors rely on hope and forget the basic principle "Primun non nocere" [a Latin phrase that means "First, do no harm"]. Even worse, some doctors rely on hype from money makers.

By contrast, look at "Less is More," in the *Archives of Internal Medicine.* [**Editor's note:** *The Archives of Internal Medicine* is an international journal of peer-reviewed articles on research in internal medicine. It is published twice a month. "Less is More," a recurring feature, reports "cases in which less health care results in better health." http://archinte.ama-assn.org.] This brilliant section highlights patient safety issues associated with adverse events and the overuse of unnecessary medical care. Progress leads to positive health gains but there are inevitably inappropriate applications. Now the degree of inappropriateness is a major concern.

WFR: Servier's drug Mediator stayed on the market for 33 years, causing nearly 2,000 deaths during that time frame, until finally being removed in 2009 [**Editor's note:** You can read more about the case at: http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)60334-6/fulltext)]. How common is it for the physician-corporate conflicts of interest to endanger people's health—i.e., doctors prescribing drugs that were not adequately tested for safety and efficacy? More importantly, how hopeful are you that scandals such as the one surrounding Mediator will lead to reforms that will make such tragedies less common?

Braillon: The Mediator scandal is not an isolated one. The European Medicines Agency (EMA) granted a marketing authorization for vinflunine in June 2009 despite Bristol Pharmaceuticals having previously said that it hoped to submit the drug to the FDA in 2008 but had given up.

The regulatory process before patient access to drugs is complex, but the principle is simple: Raise the bar for drug approval. This is just common sense. Agencies must protect the patients, not the interests of companies concerned by their impatient shareholders. Indulgency or hopes are not the solution.

Anti-cancer drugs are one example among many. The industry had aggressively managed to lower the level of drug benefit used for cancer drug approval. This results in accelerated approval. Richard Pazdur, the FDA director for oncology drugs products, had repeatedly, over a long span of time, insisted that the bar was too low. He showed that clinical benefit was confirmed in only one out of two post-approval trials and that many ineffective drugs remain on the market for an unacceptable time to the exclusive benefit of the manufacturer (the early approval process allows an incredible mean saving of five years in terms of availability on the market).

WFR: Europe's governments and the U.S. government are all struggling economically right now, and most of them anticipate substantially cutting their expenditures over the next few years and maybe even longer. If money is that scarce, then governments might be less able to (1) support honest medical research, (2) support health care infrastruc-

ture in general, and (3) police private industries to make sure that they are not unduly corrupting medicine. In that case, physicians and health facilities could become even more dependent on corporate patronage and even more susceptible to excess corporate influence. What do you think?

Braillon: First, there many priorities: justice, education, etc. Health care is not the only one. Indeed, money is always scarce and the present crisis should not be used as an excuse for governments to accede to excess corporate influence.

But as taxpayers, we know that the system can perform far better. The model must be more efficient. The cost of non-quality is incredible. Non-quality is not only waste, but damage. The United States ranks first in the world for health-care spending ($8,000 per capita, 17.4% of Gross Domestic Product) but benchmarks consistently show that the United States underperforms both on health outcomes and access, compared to other countries. In contrast, the United Kingdom spends only $3,500 per capita and 9.8% of GDP for health care but ranks among the very best for performance.

Indeed, research must be stimulated, but blindly pouring out money is not the solution. Taxes reduction is a simpler incentive to help promote research.

Regarding corruption by private industry, laws must be implemented and enforced. Public Citizen has made the diagnosis: "While the defense industry used to be the biggest defrauder of the federal government under the False Claims Act (FCA), a law enacted in 1863 to prevent military contractor fraud, the pharmaceutical industry has greatly overtaken the defense industry."

Settlements for criminal and civil monetary penalties reached a total of $20 billion in penalties during the 1991-2010 interval; three-quarters of the settlements and penalties have occurred in the 2006-2010 interval. In late 2011, Merck agreed with the U.S. Department of Justice to pay $950 million to resolve criminal and civil charges over the promotion and marketing of rofecoxib (Vioxx). Glaxo agreed for $3 billion to the U.S. government to settle civil and criminal investigations into its sales practices for numerous drugs. It is Glaxo's fourth case since April 2008. Now Glaxo also ranks first for the amount surpassing the previous record of $2.3 billion by Pfizer in 2009.

These may seem large amounts but they have clearly failed to encourage good corporate practice. The FCA is only compensatory and not punitive. The $2.3 billion for Pfizer represented only a small proportion of its overall profits, given that Bextra was marketed from 2001 to 2005 and the company's profit for the first quarter of 2011 alone was U.S. $2.2 billion.

Clearly, pharmaceutical companies cope with the FCA—their huge profits largely compensate for the settlements. Non-punitive anti-fraud laws do not stop pharmaceutical companies from engaging in fraudulent activities.

WFR: To what degree can the public university labs or the "angel" firms, which assist cash-poor researchers, provide viable alternatives and counterweights to the corporations? Or, to what degree are doctors truly dependent on the established pharmaceutical industry?

Braillon: Angels are not the solution. They are too few, and as you know, angels are sterile: They cannot reproduce themselves. The system should maintain a position stimulating both independence and performance.

The pharmaceutical industry spends more on marketing than on research. This is a major problem. It is not just advertising; it is also the recruiting of "Key Opinion Leaders" from the universities. "Key Opinion Leader" is a commonplace euphemism used for famous professors recruited by "pharmarketers," which means in fact "Golden Opinion Molders."

The $19 million in payments over a few years to Dr. Thomas A. Zdeblick (chairman of the University of Wisconsin's Department of Orthopedics and the editor of the *Journal of Spinal Disorders and Techniques*) by Medtronic is one example among many. Moreover, no one can ignore now that health care is a capitalist good, so long as physicians are paid based on the volume of their activity. It's very uncomfortable for doctors and hospitals to consider that they are creating undue demand, but they are.

A century ago, George Bernard Shaw noticed: "That any sane nation, having observed that you could provide for the supply of bread by giving bakers a pecuniary interest in baking for you, should go on to give a surgeon a pecuniary interest in cutting off your leg, is enough to make one despair of political humanity." The solution is the first point among Shaw's 14-points conclusions: Nothing is more dangerous than a poor doctor; not even a poor employer or a poor landlord.

Laws can help, but they have to be clear, implemented with investigations and adequate penalties, and regularly updated. In reality, existing laws are not very effective. Laws are a prerequisite to increase our awareness, not to reassure us. The Sarbanes–Oxley Act of 2002 did not prevent the Enron and Andersen Consulting (now Accenture) scandal, and recurrence was no surprise: In 2010, Lehman Brothers used Enron-style balance sheet tricks. Laws and regulations without significant penalties can neither prevent fraud nor institute fairness within a regulated industry.

For professionalism, we must avoid byzantine discussions on the acceptable limits of conflicts of interest. The simplest, such as "No free lunch" launched by Bob Goodman, is the most effective initiative. This must concern all health care providers, trainees, and students.

The Australian medical journal *Emergency Medicine Australasia* announced in February 2011 that it has "stopped all drug advertising forthwith" and has called on similar publications to do the same. It is easy to avoid conflicts of interest! Professionalism can be easily summarized: loyalty to the patient. Is it so difficult to put the patients' interests first, to respect them by assisting in making rational choices about their own lives? What would you say if policemen and judges were engaged in continuing education programs in exotic places paid for by those who run private jails?

Independent experts and doctors who highlight problems in the system are facing more and more severe and better-organized attacks. "The world is a dangerous place to live; not because of the people who are evil, but because of the people who don't do anything," according to Einstein. Whistleblowers efficiently protect the people. That is why they are attacked. They must be protected.

Lastly, consumer groups must act to protect their own interests. They must be pro-active, educate themselves, and recruit their experts. Life is about interests. Lobbies are neither clever, nor honest: but they naturally protect their interests. Patients must organize themselves and protect their interest as effectively as the lobbies do. Worryingly, more and more groups now receive funding from the industry, as the law allows companies to communicate directly with patients about their products.

When will direct-to-consumer advertising be banned? It is time to close this Pandora's box opened in 1997. Indeed, spending on DTCA for prescription drugs in the United States has increased dramatically over the last decade and the flow on the Internet is out of control. Regarding laws, class actions foster consumer protection. Sadly, they are now almost impossible in France, and this is probably not a matter of chance.