Introduction

A TALE FROM THE INSIDE AND A VIEW FROM THE EDGE

On a spring day in 1960 I found myself on a Dutch train, bound for the German frontier, in the company of an Irish-American physician. Both of us worked for our respective divisions of a venerable drug company with its offices in North Carolina. I myself, newly qualified in medicine and law, was still feeling my way as a novice in the unfamiliar world of pharmaceutical commerce, from the vantage point of a desk in Rotterdam around which the channels of business frothed and flowed. My travelling companion held a medical directorship with the parent company. Now he was on his way to a vital meeting in Germany; I was merely there to speed him on his way to the border. His mission, as he confided in me with some pride, was to secure a licence for North America on a major new pharmaceutical, a revolutionary sleeping remedy. Devoid of unpleasant effects, it could be used with confidence by the ill, the aged, by children, by women in pregnancy. As the train slowed for the border station at Nijmegen, he waxed ever more enthusiastic. I took my leave of him as we changed trains, very prone now to believe that I had been privileged to glimpse the dawn of a wondrous new era. Insomnia, I knew, was a plague of the city masses. Was the solution now indeed so close at hand?

Back at my steel desk in Rotterdam, the medicines on which my daily duties centred were more mundane. For the moment there was little more to demand my attention than a series of famous old remedies for relieving coughs and colds; even the most astute of the advertising people with whom I worked could not find a great deal of excitement in them when addressing messages to the public. But there were delightful individuals on every side – my colleagues, the extroverted advertising folk from Madison Avenue who flew in to disburse American experience in promoting commerce, the good-humoured production engineers with their weighty protocols. Even a life that for the moment was centred on cold rubs and cough syrups (though with promises of appetite suppressants, bone replacement materials and a wondrous cholesterol-reducing
drug yet to come) was in that way enjoyable, if not tremendously serious. All the people around me had wives and children and dogs and cats and they found the business exciting, if only because there was a competing cold rub being sold down the road and it would be fun to get the better of it. True, they found it tempting now and again to stretch the truth a trifle (anguished mother portrayed in advertisement: “Is it perhaps my fault that my baby still has a cold?”), but there was no wickedness, just a degree of mischievousness. Yes, the British daughter company had quietly started adding morphine to its over-the-counter cough syrup, but that was surely only a temporary aberration, and Whitehall was bound to stop them sooner or later. And yes, the people in the Canadian branch were about to be prosecuted for claiming (with a dubious quotation from Linus Pauling) that the mere trace of vitamin C that they put in their sugary cough drops would cure the common cold; but we in Rotterdam considered ourselves too sensible to do anything quite like that.

Sheer boredom with coughs and colds, and the slowness with which my promised research tasks developed, led me only months later to move to another company, this time a European pillar of industrial respectability with a solid research base. Yet from time to time I had reason to look back to the point where I had experienced my first encounter with the pharmaceutical industry – look back and sometimes wonder. First there were the black newspaper headlines now emerging about that exquisite sleeping remedy to which I had once been introduced in a train; hundreds – and in due course thousands – of children in Germany and elsewhere had been born without functioning arms and legs after their pregnant mothers had taken the drug. My one-time companion in the train had managed to slip the drug onto the Canadian market, with similar tragic results – heaven be praised, the Food and Drug Administration had stopped it in America before it had a chance to do any harm on that side of the border.1 And then there was that cholesterol-reducing drug – could it be true, as the journals were now reporting, that the American company’s researchers had detected its horrifying side effects in laboratory animals, and had promptly destroyed the animals to be rid of the inconvenience?2 Unfortunately it was true. My one-time employer, for whom I had known true affection, faded from the scene in a haze of doubt and disgrace, soon to become a mere branch of a soap company. Somehow, looking back to that time, I am reminded of Mr Justice

Sheen’s verdict on that horrific disaster involving the *Herald of Free Enterprise* car ferry off the French coast in 1987: “the body corporate was infected with the disease of sloppiness”.3 They say that cleanliness is next to godliness; perhaps sloppiness is next to wickedness; somehow, I had nearly brushed up against it.

My next 11 years were spent in the generous arms of the serious Dutch pharmaceutical company that was my new home, advancing on my way until I was awarded a senior medical and scientific post. The elderly Austrian professor who had blessed my initial appointment was a man of enviable repute and great achievements – but was the twinkle in his eye not a clue to some innate mischievousness on his part too? The years brought worthwhile scientific achievements to the group which I managed and I believe that we well deserved our success. With our horizontal form of management – shifting potential medicines almost seamlessly from the chemical laboratory to the pharmacologists and thence on to the clinicians – we surely attained more than one could ever have managed in a compartmentalized university environment. But as my ageing mentor retired and the bright-eyed young men from the business school moved into the oak-panelled offices, it was as if the curtain that shielded us in our cosseted research world from all that was vaguely improper or frankly sinful sometimes seemed to be growing very tattered.

Some of the new arrivals in and around the boardroom were honest salesmen whom I could respect. But others caused much headshaking in my circle. Flexible ethics … naughtiness … mischievousness … sloppiness … Was there perhaps a slippery slope close at hand? There was soon a tale going the rounds about our agents selling appetite stimulants to starving children on the Indian subcontinent (“Not with our specific approval, naturally, but it’s difficult to set hard and fast rules for these things, you know.”) Then there was the day when an untruthful draft advertisement that I had firmly turned down somehow slipped through to the printers (“So sorry, but you were out of reach that week”). And then there were those troublesome dogs that developed tumours when taking one of the company’s best-sellers – somehow both they and the laboratory protocols that belonged with them were quietly spirited away behind my back into that distant other-world where inconvenient (“but quite possibly misleading?”) reports are said to belong. It was time for me to move on.

If my subsequent decade in the world of national drug regulation taught me anything, it was that the faces of industry are so very diverse.

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Facing one firm after another at hearings across the green baize table, it was rewarding to meet first-class industrial researchers who had truly helped to relieve the lot of sufferers from Parkinsonism, glaucoma or hypertension. As government regulators, we were often respected by such people and our role appreciated. Yet there were also the figures who set out to bamboozle us; they seemed to live in the naive supposition that since we were mere civil servants who had never been to a proper business school we could easily be led up the garden path – or perhaps even eased towards leniency by a small financial consideration? There were also the moments when all the might of big business thundered up to our table, indignant that we were standing in the way of some supposed scientific breakthrough, and ready to drop dark hints of recourse to the minister if we persisted in our foolishness. We did indeed make the occasional mistake, but over the years a succession of ministers supported our judgements and we saved a lot of lives, quite apart from protecting some businesses from the consequences of their own foolishness.

After a decade I moved smoothly from national regulation into the rarefied but rich atmosphere of the World Health Organization. I remember well the condescending smile with which some of my one-time colleagues in industry tended to look at WHO; for them it was a well-meaning organization with no teeth and little pushing power. True, it had been rendered tame from its very outset by those national politicians who shuddered at the thought of anything approaching supranational authority. Yet though it might be weak in terms of formal authority, it was wise, experienced and vastly influential in other ways. The emissaries of the global drug industry might still bluster and thunder at the conference table in Geneva against any proposal to endow the World Health Organization with anything resembling true power; but behind the scenes, and particularly through its six regional offices, WHO quietly provided drug regulators from Jakarta to Reykjavik with the knowledge and experience that they needed in order to act in the public interest.

In later years, working from a solid university base, I commonly found myself as an expert witness confronting industry across a court of justice in matters of apparent drug injury, more particularly in the United States. The story of Mrs Grundberg is one that will always remain with me.

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Grundberg had chronic difficulty in falling asleep and her family doctor had prescribed her a novel hypnotic. I was familiar with the product; in my regulatory days in Europe, our committee had, to the hysterical indignation of the producer, resolutely removed it from the national market because it was clearly capable of inducing a dangerously psychotic state in a minority of users. Unhappily, Mrs Grundberg proved to belong to that wretched minority and, under circumstances which pointed all too clearly to cause and effect, she had taken the drug as prescribed and then in turn picked up a gun and shot her beloved mother eight times through the head. A criminal court dismissed a murder charge against her since she had acted under the influence of a toxic agent. The attorneys with whose aid she now sued the producer for damages had done their work in the company archives. It was documented up to the hilt that the firm had become aware of this serious side effect in the early stages of human study, but had neither warned of it nor sought to find a safe dosage level at which it would be unlikely to occur. What of the company’s lawyers, well paid to conduct an unenviable defence? There is an old saying in American legal circles: “If you can’t win on the facts, argue the law; if you can’t win on the law, argue the facts. If you can’t win on either, call the other lawyer names.” Without a leg to stand on, as regards either the law or the facts, they adopted the third course, and sought to frighten me away from the witness stand with a barrage of veiled threats, scorn and insults. It was to no avail: Mrs Grundberg won a worthy settlement, as did a series of other victims who took the firm to court. It was not the pharmaceutical industry’s most glorious day. And yet … Look back to the press records of the time and you may actually wonder whether in the long run virtue indeed prevailed. The firm found grounds to sue one of Mrs Grundberg’s witnesses for libel, and won in a British court. The convoluted press releases that followed portrayed the producer as a knight in shining armour who had been wronged throughout. Truly, public relations can be a mysterious art, setting truth about with many curious fictions.

Mischievousness … naughtiness … sloppiness … foolishness … plain wickedness – they can be hard to distinguish from one another, and the slope is indeed slippery. I have never, in the course of my various careers to date, found myself regarding the pharmaceutical business – or indeed any other acknowledged form of business – as essentially wicked.

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let alone criminal by nature. The slippery slope is however all too apparent, and it is particularly steep where competitive business is conducted on a massive scale with the prospect of large profits, and where the ultimate customers for whom the battle is being waged are distant and anonymous.

It is hardly possible, when considering the darker side of a field such as this, to confine oneself strictly to acts and omissions that lie only within the defined scope of the criminal law. That law differs from country to country and from time to time. The inability to bring a successful prosecution in the case of the *Herald of Free Enterprise* ferry disaster was understandable in view of the state of English law at that period. The outcome might perhaps have been different had Britain’s later Corporate Manslaughter and Corporate Homicide Act\(^7\) been in force at the time, though where large firms are concerned it may still be impossible to determine at which level of authority liability can be considered to lie.

No one whose interests and qualifications lead him or her to seek a career in the pharmaceutical industry, as I did many years ago, need hesitate to do so on the grounds that one may have to face ethical or legal challenges in the course of one’s work. The essential point is to recognize those challenges when one encounters them and at that point to stand firm on the side of righteousness. At a point in my own career when I was still very much committed to the industry, I published what I saw as a credo for any proper drug company, followed by one for myself:

> The fact that I shall ordinarily speak no ill in public of the firm to which I am attached is less a matter of rules than of acquired loyalty and conviction. If I encounter something with which I am not entirely comfortable, the first thing I shall do is to try and put it right. And nothing and no-one can prevent me at any moment from stepping out of the industry, if I feel the need to do so …\(^8\)

That, surely, is a fair approach for anyone who chooses to share a journey with the pharmaceutical industry; but the adherence of individual staff members to such a creed also provides a vital anchor to social morality for industry itself. The behaviour of a corporation is not determined only in oak-panelled offices; it is shaped in large measure by the ideas, convictions and self-discipline of those who serve or advise it in many

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\(^7\) United Kingdom, Corporate Manslaughter and Corporate Homicide Act (2007).

another capacity. These things, perhaps to a greater extent than laws and regulations, will surely determine the extent to which the pharmaceutical industry deserves a place as a respected and respectable element in society in the coming decades of the twenty-first century.