

## Who'd be an Industry Medic these days?

By Nick Stephens, CEO RSA

This piece reviews the role and future of industry medics. It starts with a quick look at the state of the industry 60 years ago and follows with a brief review of the thalidomide tragedy. From there it looks at the regulatory regime that followed and its impact on industry medics. It then looks at what has happened in the last 10 – 15 years and concludes with a brief look at the future for industry medics and what they need to do about it.

### **The emergence of the modern pharmaceutical industry**

It's now more than 50 years since the modern pharmaceutical industry began to emerge. In those days it had a reputation for being peopled by eccentrics, powerful personalities and scoundrels.

Russell Marker probably typifies the eccentrics. Deep in the Mexican jungle in 1944 he worked at synthesising progesterone from the native yam. Having succeeded, he set up Syntex before storming off with his bat – and his notebooks – in a dispute over money.

Syntex then replaced Marker with Giorg Rosenkranz, a Hungarian expert in steroid research and a strong personality. Rosenkranz had to figure out how to recreate Marker's chemical production processes. He succeeded against all odds and went on to become chairman of Syntex until 1982. He is still active in the industry at the age of 90.

At this time Wyeth had its own powerful personality. Alvin G Brush, a certified public accountant who knew where every penny went, had been CEO for 10 years and would go on to complete 30 years in the role. It was a long reign and it allowed him to stamp his mark on the company and to mould its character and culture.

GSK was still just Glaxo in those days, known best for its baby milk formula. Its strong personalities would come later. The aristocratic Sir Austin Bide in the 70s. The accountant and economist Sir Paul Girolami in the 80s. And the scientist Sir Richard Sykes in the 90s.

The scoundrels were apparently the industry's doctors. In those days many clinicians had a low opinion of doctors in the industry. I wasn't around at the time to observe this myself. But the founder of RSA, my father, was an executive in the industry in the 70s and found lingering traces of this perception. Many considered the industry itself as the last refuge for scoundrels from the profession – a place to which doctors would gravitate when they became unreliable in the clinic. Indeed I remember a well-known professor of medicine once saying to me "he has a bit of an alcohol problem

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but he'll be all right for the industry".

All that was about to change. The late 50s and early 60s brought the Thalidomide tragedy. Most people know the story of this tragedy but I'd like to revisit it briefly – for two reasons.

### **Thalidomide**

First, it was a seminal event in the evolution of the modern pharmaceutical industry. It had a singular impact on the role of medics in the industry, and – in time – on their calibre and repute.

Second, some of the lessons that came out of it are still relevant today. Also, to some extent, it helps to set our modern concerns about regulation into historical perspective.

Thalidomide first appeared on the market in 1957. Chemie Grünenthal, a German company, promoted it as a sedative and as a treatment for morning sickness in pregnant women. The company sold it between 1957 and 1961, mainly in Germany and Britain. It was also available in about 40 other countries under various brand names – but not in the USA.

In 1960 Grünenthal decided to market it in the USA and teamed up with Richardson-Merrell of Cincinnati to apply to the Food and Drug Administration for approval. When the FDA received Richardson-Merrell's application it assigned it to its newest reviewer, Frances Oldham Kelsey. The thinking was that it would not be a controversial application and therefore a good one for a new reviewer.

Prior to qualifying as a physician, Kelsey had earned degrees in pharmacology and worked on pharmacological research. After reviewing the application Kelsey expressed concern about the lack of adequate toxicity data. She had previously completed animal toxicity studies, including studies in pregnancy, and she refused to clear the product for marketing. Instead she held out for more toxicity data.

The decision brought her enormous pressure from Richardson-Merrell in the form of phone calls, letters and visits demanding approval. Nonetheless she held firm on her demands for more toxicity data. The firm sent further information in response to her requests but none of it satisfied her. She was to claim later that most of this information was little more than testimonials rather than data from properly executed studies.

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Joseph Murray from Richardson-Merrell tried to intimidate her by complaining to her superiors that she was unreasonable and nit-picking. He was also making frequent phone calls and personal visits, some of them unannounced, all of them demanding approval for the product.

Meanwhile evidence was emerging from around the world of a problem. First there was a letter in the BMJ from a doctor who had reported seeing cases of peripheral neuritis in patients on thalidomide. This rang alarm bells in Kelsey's head. She suspected that a drug that could damage nerves could also affect a developing foetus – notwithstanding the belief at that time that the placenta was an effective barrier. Her suspicions soon proved to be grimly accurate.

Then physicians across Europe began reporting that a lot of women were giving birth to horribly deformed babies, but none of them yet knew why. In late 1961 a paediatrician in Germany and an obstetrician in Australia independently made the connection between the birth defects and thalidomide.

Shortly afterwards the German authorities pulled the product off the market and other countries soon followed. Finally, Richardson-Merrell withdrew its application. Kelsey never had to make a decision to reject it.

Worldwide, more than 10,000 babies were born with serious deformities. The number in America was 17.

### **The new regulatory regime**

There followed a swift and radical overhaul of the way drugs are regulated.

In 1962 the US Congress passed new legislation that strengthened the FDA's control over drugs. Now they required "stricter limits on the testing and distribution of new drugs" and determined that "effectiveness required to be established prior to marketing." Testing would have to be much more rigorous and data would have to be much more comprehensive.

1. Bren, Linda, "Frances Oldham Kelsey: FDA Medical Reviewer Leaves Her Mark on History", FDA Consumer magazine, US Food and Drug Administration, 28.02.2001
2. Lenz W. Kindliche Mißbildungen nach Medikament-Einnahme während der Gravidat [Malformations in children after a drug taken during pregnancy]. Deutsche Medizinische Wochenschrift.1961; 86 :2555 –2556  
McBride WG. Thalidomide and congenital anomalies. Lancet.1961; ii :1358

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Other countries brought in similar regimes. In the UK we got the Medicines Acts. Thus came about a sea change in the way pharmaceutical companies operate, the roles that industry doctors perform, and ultimately the calibre and repute of pharmaceutical physicians.

More rigorous testing of drugs and more demanding requirements for data would have profound implications for the role of the industry medic. A new breed of pharmaceutical physician would eventually emerge.

Inside a generation, perceptions had changed completely. The scoundrels and unreliaables described to my father had gone. In their place were some of the best and brightest doctors from clinical medicine. The evolution in the industry meant that it had begun to attract them.

By the time I started recruiting them full-time in the 1990s their work was of indisputably high quality. And they were much more than the ethical voice of the company. They were also valuable business partners.

So what had attracted such good people to the industry? What was pushing them out of the clinic? And what has changed for them in recent times?

We think we know some of the answers. These come partly from our experience of dealing with doctors practically every day for the last 25 years. And they come partly from the data we keep, including data on pay – in the hospital and GP sectors as well as the industry.

### **Industry attractions**

The list of attractants would include variety and intellectual challenge, money, recognition, team working, clear purpose, common goals, progression, good working environment and proper resources.

The push factors would include poor working conditions, conveyor belt careers, over-specialisation, no team work and no common goals.

Our opinions on these matters – however well supported by data – are one thing. The voices of doctors themselves are another. In 2000 Mark Watling carried out a survey for BrAPP among doctors with relatively short experience in the industry. It produced broadly similar answers.

Variety and intellectual challenge were at the top of everyone's list. In the survey, more than 80% of respondents rated the intellectual challenge factor highly. More than 67% have it the highest possible rating.

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We talked to several medical directors in preparation for this article and everyone we spoke to said the same thing about intellectual challenge. Typical of their comments was this one. “To stay effective you had to be constantly learning. It was a constantly changing environment so you couldn’t get bored.”

Another medical director was clear that variety and challenge were the key things for him too. “I’m a restless individual. I always have to have a new intellectual challenge.” And he added that the industry offered more than the opportunity to apply medical knowledge and knowledge of the environment. Medical minds are trained minds and “you can add value by getting involved just using your logical thought processes.”

Money was also a factor in the BrAPP survey, but it came a long way behind intellectual challenge. And it wasn’t the same for everyone. Whether you got more, the same or less depended on when you joined. To be more specific, on the state of supply and demand at the time.

The survey showed that just under 20% of respondents joined the industry for the same or less money. They would make up the ground or get ahead in two years or so. More than 80% got more money from the start. More than 50% improved their earnings at the outset by 40% or more.

One of our medical directors did particularly well. He was a senior registrar when he got an offer to join the industry in 1983. His wife, also a doctor, had just become pregnant and they faced the prospect of losing half their joint income. The offer was enough to restore their full joint income, meaning he effectively doubled his pay. But it was clear from other comments he made that the pay increase was only one of the deciding factors for him. “As a junior investigator in a company-sponsored study (my boss was the principal investigator) I had seen what the industry had to offer. There was variety, challenge and flexibility. And I could pursue my interest in my specialism, finally becoming a consultant while working in industry.”

Working conditions were another factor. Another of our medical directors was doing the MRCP exams at the same time as a 1 in 3 rota. “The industry offered quality of life and regular hours in addition to the challenge and mental stimulation that I needed.”

And then there was the conveyor belt career, or sometimes the lack of one. Another of our contributors observed that “NHS consultant posts were a case of ‘dead men’s shoes’ before the Calman report.” She also found that the industry gave her “opportunities to improve healthcare for the majority rather

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than just the individual.” (I’m glad she didn’t say “for the many and not the few”!)

Team working was another attraction. One medic who joined the industry some time ago spent much of his first two years working with and learning about manufacturing, quality assurance and reg affairs. “I was being trained to make medical risk assessments of issues in those areas. And I could also give medically informed advice on PR.”

I could go on – but you get the picture. It’s time to look at what’s changed over the last 10 years or so and how these changes have affected industry medics.

### **Changes since the 90s**

A simple list of changes would include more regulation, the clinical trial environment, litigation and class actions, cost containment including the role of NICE, changes at the GMC, safety, and harder penalties.

There has undoubtedly been more regulation, apparently increasing at an exponential rate. Some of it has been aimed at further safety, but a lot has been about creating more hurdles for the industry to jump on reimbursement. Behind that, according to one of our senior industry medics, is the fact that “the NHS cannot cope with the huge increase in the cost of new drugs, plus people are living longer.”

Another aspect of increasing regulation has been its more aggressive approach to compliance. In the quest for 100% compliance, internal and external scrutiny has grown logarithmically. In consequence the role of the medical director in trying to ensure compliance has grown hugely. According to one of our contributors “There is increasing enforcement of Good Clinical Practice and standard operating procedures.”

For some industry medics, the practical aspects of this make them feel that they are becoming tick-box mechanics. They find that deeply unsatisfying.

The changes have made reg affairs a much more critical aspect, and one that poses tricky questions about staffing and training in that area. At the bottom of the pyramid, reg affairs attracts people who like its structured, rule-bound character. However at its apex it needs people whose skill is in knowing (or figuring out) how to get the most out of the rules by working their way through them and working with those who make them. This implies some difficult adjustments as their careers develop – which also has implications for the medics working alongside them.

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And at the medico-marketing interface there are more challenges. It is now much tougher dealing with advertising, sponsorship and relations with doctors in the clinic.

But it seems the challenges are not all created by our own bureaucracies. There is also what one senior industry medic described as US cultural imperialism. The USA has always been the largest market for pharma and always in a strong position vis a vis the UK. What has changed is its former tolerance of others doing things a different way. Some of you feel it now flexes its muscles a lot more in pursuit of a 'one size fits all' approach to things medical.

The clinical trial environment has changed significantly. It involves a lot more bureaucracy – which makes it harder to do clinical trials quickly and easily. The role of the MHRA has grown, with much more pre-vetting of new products. According to another senior medic in the industry, “it (the MHRA) would say that it has changed for the better, but it lacks pragmatism. There is a risk of over-communicating with doctors on safety matters.”

Then there is outsourcing. A lot of clinical trials are now contracted out to specialist agencies. Not only that but, according to some of you, “Clinical research is now very structured with little scope for innovation.” The combination of these two factors makes for a further lack of satisfaction for industry medics.

What's more, the rising costs of clinical research in the UK, added to increased regulation and the concomitant delays in getting studies started, is resulting in less of the work being done in the UK. One of our senior industry medics observed that “Some hospital R & D boards are stopping research from being done – on cost grounds.” None of this bodes well for the future.

Litigation and class actions have wrought havoc with the industry as we used to know it. Vioxx is just one case in point. Some of the landmark cases involve amounts up to \$20bn – making senior executives very jittery as well as ultra-conservative. One consequence is that top execs now spend a lot more time talking to their lawyers than they do talking to their senior medics. Another is that those same senior medics find themselves doing a lot more work of a defensive and negative character – and often being pressed into service late in the day to do it.

Part of the reason for the increase in litigation is that, according to another senior medic in the industry, “There is more information out there and there

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has therefore been an evolution in the expectations of the public. So there are more class actions. The industry is more global and information is more global.”

Cost containment is undoubtedly one of the main goals of the burgeoning regulatory regime – for the sort of reasons adduced earlier by one of our lady contributors. NICE is but one example – and, according to some, an example of a misnomer. There was a letter in one of the broadsheets recently, arguing that NICE should be re-named the National Institute for Clinical Economy. It was from someone terminally ill who couldn’t get an expensive medication. He wasn’t bitter; he understood the language of priorities – he just couldn’t take the dishonesty and hypocrisy involved.

For some of you, part of the problem here is that too many me-too products are still sucking up public funds. That leaves too little scope to reimburse the sort of innovative products that have turned conditions like HIV from a death sentence into a controllable condition inside a couple of decades.

How we deal with that is difficult. The status quo is good for pharma shareholders, but not for patients or the pharma employees striving to help them. Finding a solution to this dilemma is one of the great challenges facing the pharma industry. Industry medics have a choice. They can leave it to someone else to solve, or they can pitch in with their own ideas and suggestions.

### **Changes at the GMC**

This issue exercised the minds of a number of you, but one in particular was about as outspoken as it’s possible to be on any issue involving professional roles and standards.

“Medics are being quietly undermined” was his opening remark. “Medicine is now very protocol-driven. Doctors are being converted from professionals who make judgments into technicians who follow protocols. The notion of a selfgoverning profession is going out of the window. The GMC is losing powers to the government.”

Now, that should make a tasty subject for an Oxford Union-type debate.

### **The Money**

So, are industry medics still ahead of the game in money terms? Short answer, No! Here’s a selection of opinions from some of our contributors.

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“Junior doctors in the NHS no longer have the long hours of times past and their pay is better. Their training is different. General Practice is now an attractive option. It’s a job for life with a guaranteed pension. The industry has been overtaken. The boom years are over for the industry; it’s contracting. Sales forces are being reduced. Pipelines are thin.”

“The money is not that good anymore. Flexibility is not that good either.”

“Fewer medics want to join the industry. It no longer has the same attractions; there is less flexibility and financial rewards are poorer. Instead there are more hurdles: cost containment, compliance and more process – to name just a few!!!!”

I have tax data for 300 GP practices detailing their incomes, as well as our internal data on Medical Directors / VPs. These data strongly support the above assertions about money.

### **The future for industry medics**

All of the changes described here have implications for the role of industry medics, their future and the way they work and get recompensed for their expertise. The prognosis does not look good right now, but remember our forebears have been here before.

Here are a few diagnoses, prescriptions and prognoses from some more of our trusty medical directors.

“There are fewer opportunities than there were 10 years ago. Fewer medics are coming in at the bottom of the pyramid.”

“The role is now a lot more informational and persuasive – albeit backed by technical skills. Our challenge is to find people who can interface with customers and stakeholders such as the DoH whilst offering leadership and other professional skills.”

“It’s difficult to have any breadth of activity. You are increasingly a specialist in a very small area. As big pharma gets bigger, the jobs in it get smaller.” So, it would seem that over-specialisation has now migrated to the industry.

“Fewer medics are now interested in joining the industry. There are now better financial rewards in the NHS.”

“New regulations have brought a threat to industry medics. From 2006

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pharmacists can do ABPI sign off of promo materials (under the guidance of a medic). Pharmacists are cheaper than medics and probably easier to get hold of. This could squeeze medics out of junior positions in companies where this is a large part of the workload. In the long run it could be a factor in limiting the opportunities for medics in the industry.”

“The people I talk to fall into two categories. There are the complacent, who don’t care about what is going on and will just take the money. And the unhappy, who find their current role unsatisfying. A lot of their time is taken up with crisis management, fire-fighting and sweeping up. We need to offer them something better.”

#### **For better or worse**

So, on balance, are things better or worse?

Well, some of you think some of the changes are for the better. One of the positive changes, thinks one medical director, is that there has been “a clamping down on unethical behaviour and excessive hospitality.”

And “safety has improved by leaps and bounds” thinks another.

Some of you are pleased to see some improvement in self-regulation. The ABPI seems to have acquired some teeth, for example throwing out Abbott – albeit for only six months.

And you feel that good things still come out of the industry, one example being the development of treatments for HIV mentioned earlier.

But the positives are heavily outweighed by the negatives, as the illustrations and quotations in this piece demonstrate. Overall the industry medic’s job has become a lot more difficult and a lot less satisfying.

Well, the question was “Who’d be an industry medic these days?” so you might expect the answer to be “Not many”. Paradoxically, it seems that the answer is quite a number of you, judging by the following comments.

“I’m talking to lots of people and I’m not letting regulation get me down.”

“You can still have a good career in the industry but you have to accept that changes are here to stay and there will be more of them. But, for part of your career, you must go and work in the USA; it’s the biggest market and calls all the tunes.”

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“The industry is one that produces drugs to treat patients but there are very few medics in high places. One of our challenges is to do something about that.”

“We can still add value by making ourselves more visible as the ethical voice of the industry. We need to stand up and be counted. We need to stand our ground on ethical issues and not allow ourselves to cave in to marketing pressures.”

You all acknowledge that you can't turn the clock back and undo the changes. But some of you think there are still things you can change. One of them is to put an end to the narrowness that has come to characterise many modern medics. One of our medical directors would do this by restoring the old apprenticeship system that helped to turn out broader, more rounded contributors.

“We medical directors are largely responsible for this. We let it happen by acquiescing in many things when we should have stood up and been counted. Many of us didn't know to ask for broader training. And the Faculty could have done a lot more.

This is a clarion call for medics to wake up; to be seen to be good at all the disciplines as well as all the skills of managing time, projects and people. We should demand the training and the visits – even if we are overbusy with compliance, box-ticking and fire-fighting.”

Well, no shortage of passion there then!

So there you have it. A set of challenges for medical directors to tackle. And a set of views on how to go about it. Both are worthy of some serious debate if you are to tackle these issues together. They are issues you can't tackle effectively alone. You need to thrash out a strategy with colleagues and peers in the industry, and then go into action together.

Let the debate begin! But not just yet.

First, some final words about standing up and being counted. In the section on thalidomide I said that some of the lessons that came out of it are still relevant today. Here is one of them.

Frances Oldham Kelsey's stand against Richardson-Merrell still holds lessons for doctors today. It took enormous courage, as well as stubbornness, to deal

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with the pressure she was getting from aggressive marketeers. And she had only been in the FDA for about a month when she got the thalidomide assignment.

Nowadays, reviewers are insulated from applicant companies by various gatekeepers. In those days no such protection existed. Applicant companies had easy and direct access to reviewers – who had to fend for themselves as best they could.

Incidentally, just by way of a footnote, Kelsey retired only last year aged 90, after serving the FDA for 45 years.

If you had been in Kelsey's shoes in 1960, could you have done what she did? More to the point, if you were faced with a comparable situation now, could you make a comparable stand?

Now let the debate begin – and RSA stands ready to help you.

Nick Stephens is the CEO of RSA which is celebrating 25 years in business this year. In the new year RSA will be sponsoring a symposium on pharmaceutical physicians and the future.

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