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Making regulation responsive to commercial interests: streamlining drug industry watchdogs

John Abraham

Has the pharmaceutical industry skilfully managed to achieve an unhealthy influence over European drug regulatory agencies?

School of Social Sciences, University of Sussex, Brighton BN1 9SN

John Abraham professor

J.W.Abraham@sussex.ac.uk

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New prescription drugs are developed and tested for quality, safety, and efficacy by the pharmaceutical industry, and little or no drug testing is conducted by governments in modern industrialised countries. Governments have regulatory authorities which have a legal duty to protect public health by ensuring that new drugs are not licensed unless they are of adequate quality, safety, and efficacy (box 1). The thousands of birth deformities and deaths caused by thalidomide focused public and professional concerns on how the commercial interests of pharmaceutical companies may diverge from, or conflict with, the interests of patients and public health. The reasoning behind the creation of new government regulatory authorities in the post-thalidomide era was therefore that they should be "entirely independent" of the commercial interests of the pharmaceutical industry and should act on behalf of the public interest by checking the adequacy of the test data produced by the industry.¹⁻³ I explain how these government regulatory authorities in the European Union, which were initially established to provide independent scrutiny of pharmaceutical firms in the interests of public health, have become increasingly responsive to the commercial interests of the industry (box 2).

Methods

The arguments in this paper are derived from electronic searches of the medical and pharmaceutical literature, combined with interviews with industry, regulators, and other professionals in Europe.

Accusing the regulatory authorities of slowness and inefficiency

The first stage in imputing slowness and inefficiency to regulatory authorities was to claim that new drugs were not being approved fast enough: this the Association of the British Pharmaceutical Industry did during the 1980s. The industry claimed that delaying approvals was detrimental to the British economy because it resulted in drug development work going abroad.⁴ In Germany and Sweden the pharmaceutical industry also pressed for quicker drug approvals.⁵

Summary points

After the thalidomide disaster the public expected drug regulation would be independent of the interests of the pharmaceutical industry

In the past 15 years the regulatory agencies have been overly influenced by the industry's desire for rapid drug approvals

Regulatory agencies have become heavily dependent on industry fees for their survival

National agencies now find themselves competing with each other for industry fees for regulatory work

European governments accepted these industry perspectives, although new drugs had in fact come to the UK or German markets in 1972-83, faster than in France, Italy, Sweden, or the United States, and more new drugs were first marketed in the United Kingdom or Germany in 1961-85 than in Austria, the Benelux countries, the eastern European countries, Italy, Scandinavia, Spain, Switzerland, or the United States (figs 1 and 2).⁶ Indeed, in 1988, the United Kingdom was found to have the fastest approval times for new drugs in the European Union.⁷ Moreover, in 1989, German regulatory staff argued that the speed of drug approvals was but a crude measure of efficiency, and that the drug review process was not delaying any

Box 1: Stages in drug development that regulatory agencies should check

- Chemical and laboratory analysis
- Non-clinical pharmacology and animal toxicology
- Phase I trials with healthy human volunteers
- Phase II clinical trials with small numbers of patients
- Phase III clinical trials with more extensive patient numbers
- Phase IV post-marketing pharmacovigilance

Box 2: Stages of increasing influence of the drugs industry on regulatory agencies

- Credibility of regulatory agencies becomes undermined by suggestions that the need to take extra time to check data shows inefficiency
- Regulatory agencies become increasingly dependent on funding from industry for development and running costs
- The drugs industry is allowed a central role in setting the priorities for regulatory agencies—for example, rapid approval times for new drugs
- Creation of an environment, such as the European Union’s mutual recognition procedure, in which regulatory agencies compete with each other for “regulatory business”

genuine therapeutic advances because the backlog related only to products for which existing treatments were adequate.⁸⁻¹¹

Some Swedish regulators have argued that, even if some regulatory authorities were slower in approving drugs than others, this could be because they were under-resourced, rather than inefficient. In Britain, for example, from the late 1970s to 1986, staff levels in the

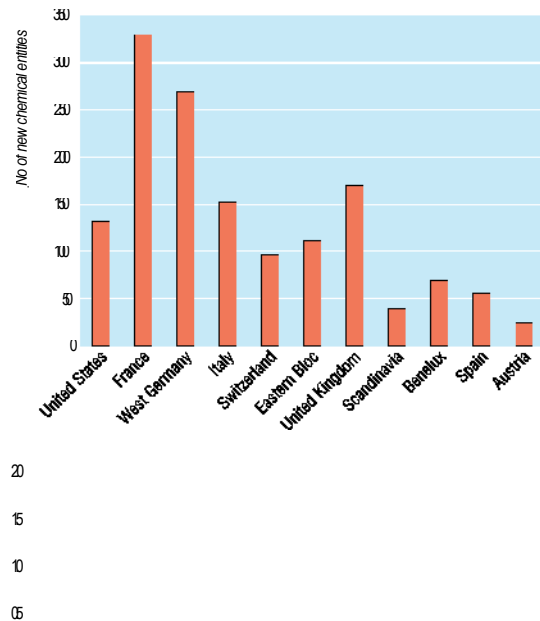
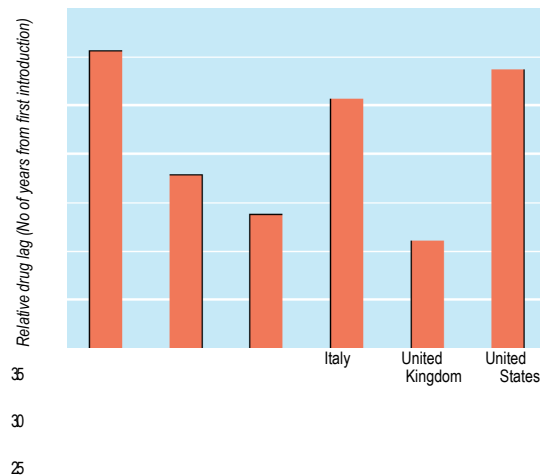
0 Sweden France West Germany
Country

Fig 1 Relative lag periods for new drugs (new chemical entities) introduced in six countries, 1972-83

Country of first introduction

Fig 2 Numbers of new drugs (new chemical entities) by country of first introduction, 1961-85

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regulatory authority grew by only 9% while licence applications increased by 87%. In the late 1980s, the American drug regulatory agency had six times as many staff handling drug applications as did its British counterpart.¹²

Making regulatory institutions more responsive to industry

European governments such as those of Germany, Sweden, and Britain decided to restructure their drug regulatory authorities in line with the industry's demands. In the late 1980s, the industry proposed that it would fund drug approvals if this would result in a "more efficient service," and called for greater informal consultation between companies and regulators.¹³⁻¹⁵ For example, in 1989 the British government accepted the industry's proposal that, to make regulation of medicines more "efficient," the regulatory authority should in future recoup all its running costs from licensing fees, rather than 60% as before. A new regulatory authority funded by the pharmaceutical industry, the Medicines Control Agency, with its own director (who came from industry), replaced the existing authority.¹⁶ Health ministers also appointed a board of experts, drawn from various quarters, including industry and the Department of Health, to advise them on the scope of the agency's targets and its performance.¹⁷ A concern to protect the commercial interests of the industry was enshrined within the agency's objectives.

In 1990, Sweden established an independent regulatory authority unit, known as the Medical Products Agency, with increased dependence on industry fees, and also a special task force to reduce the backlog of new drug applications. In 1995, the German government replaced the existing regulatory authority with the more industry-friendly federal institute for drugs and medical products,¹⁸ the staff of which were instructed to be less cautious about approving new drugs.¹⁹ Even the US drug regulatory agency became concerned about accelerating its new drug approvals relative to other regulatory authorities.²⁰

Europeanisation and interagency competition

In addition, regulatory bodies have been placed in competition with each other for industry fees, and where there are institutional incentives, not to reject new drugs. This situation arose indirectly from the Europeanisation of pharmaceutical regulation, as a result of the European Commission's adoption, to a large extent, of the industry's vision for Europeanised drug regulation. The international pharmaceutical industry is interested in European harmonisation and streamlining of drug regulation because this allows a drug to be marketed in several states more or less simultaneously, taking advantage of "efficient" fast approval rates, rather than having to negotiate with separate national regulatory regimes.

Since January 1998, new drugs can be licensed in more than one European Union country at once in one of two ways: mutual recognition or centralised procedure (box 3). To accommodate the industry's desire for more rapid approval times, a strict timescale—210 days—has been prescribed by the Euro-

Box 3: Drug regulation in multiple EU member states

One route, known as the mutual recognition procedure, enables manufacturers to seek simultaneous licensing for a new drug in two or more member states, providing that they have an existing licence for that drug in at least one, known as the reference member state. The regulatory agency of the reference state then approaches the agencies of the states in which approval is sought. Under this procedure, the regulators in the member states concerned are encouraged to agree to license the drug in their countries—that is, to mutually recognise the initial approval of the reference state. If they do not agree to do so the matter is referred to the European Commission's scientific advisory body, the Committee for Proprietary Medicinal Products, for arbitration. If the commission accepts the committee's advice then it is binding on the states concerned and on the reference state.

For biotechnology drug products, manufacturers must follow another route, known as the centralised procedure, which can also be used for highly innovative new drugs. In this procedure the advisory committee simply decides, after considering assessments by a rapporteur regulatory agency, whether the drug should be approved throughout the European Union. Any objections to the rapporteur's assessment are considered by the committee, which then makes a binding recommendation for or against an European Union-wide licence.

pean Commission for the mutual recognition procedure. Moreover, the largest amount of regulatory work (and hence the most fees from industry) comes from being the first state to which an application is submitted within the mutual recognition procedure, and being the rapporteur in the centralised procedure. As the regulatory agencies in the European Union are now largely funded by industry, and because companies look for fast approval rates as a key criterion when choosing where to submit the application for approval of a new drug, regulatory agencies are, in effect, competing with each other for "regulatory business" by attempting to approve drugs at an ever faster pace.

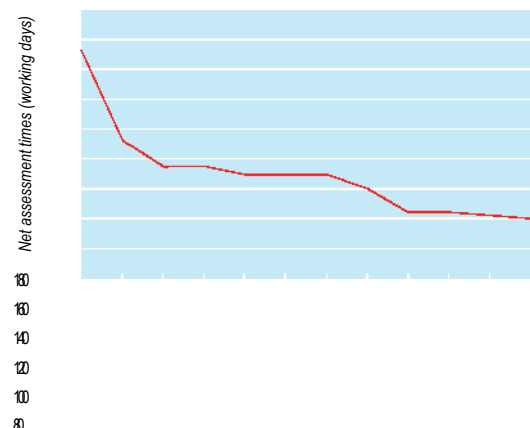
The competition for fees from industry means that regulatory agencies are not satisfied to meet the European Commission's requirement of approval or rejection within 210 days. For example, the British Medicines Control Agency's average net in-house assessment time for new drugs fell from 154 working days in 1989 to 44 days by 1998 (fig 3).⁴ The drug regulatory review times for Germany, Sweden, other EU countries, and the United States have also fallen dramatically.^{4,30} It might be argued that this competition between agencies will enhance drug safety and efficacy, but even if competition were to encourage some regulatory agencies to try to improve their safety and efficacy regulation, this would be in a context of increasingly less time for all EU regulatory agencies to check drug safety and efficacy data.

The suggestion that such interagency competition is driven by concern to improve safety and efficacy is further undermined by the fact that different approaches have been taken towards rejections of new drug applications and rejection of "old" unproved products at present on the market. The Swedish regulatory

agency has extended the response period for a company whose product licence application faced rejection from six weeks to three months. Meanwhile, in Germany, "old" products, whose efficacy has never been demonstrated against the modern standards of the 1976 German drug law, were granted extended "licences of right" until 2004. Despite the potential disadvantages of these measures for the public, they were not regarded by the government authorities as "inefficient."⁴ Evidently, the time taken for regulatory processes and decision making may be extended rather than accelerated if this is in the interests of the industry.

Moreover, under the mutual recognition procedure, a heavy emphasis on widening the scope of new drug approvals coexists with institutional incentives not to block approval. If a member state does not wish to accord mutual recognition to the approval of a new drug by another member state on public health grounds, it must immediately inform the company, the reference member state, the other member states concerned, and the Committee for Proprietary Medicinal Products, stating the reasons for its decision and indicating how the gaps it perceives in the new drug application might be filled so as to facilitate mutual recognition. A compulsory conciliation stage then follows to facilitate the member state's recognition of the reference member state's approval.⁴ Thus, regulators are under pressure to adopt quickly a position on the reference member state's approval, and to assemble robust supporting evidence if they propose to reject an application on public health grounds. There is no such pressure if they intend to mutually recognise the reference member state's approval.

It might be argued that the acceleration of approval times for new drugs has been adopted so that patients can gain faster access to new treatments such as anti-AIDS drugs. In Europe, evidence to support this hypothesis is at best scanty compared with the evidence that the rapid drug approval times have been a consequence of making regulatory agencies responsive to the commercial interests of the pharmaceutical industry. Fast tracking of genuinely needed drugs can accommodate this demand from patients. Furthermore, if the acceleration of approval times for new drugs was genuinely driven by a desire to provide faster access to new treatments, a concomitant introduction of regulatory requirements for comparative efficacy testing would be required to show that a new drug offers a real advance. Yet neither the



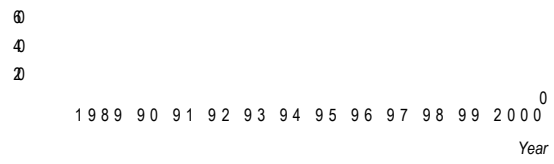


Fig 3 Decreasing approval times for new drugs at the UK Medicines Control Agency, 1989-2000

European Commission nor the governments of the European Union, North America, or Japan have introduced such requirements, even though this would help bodies, such as the National Institute of Clinical Excellence in Britain, to assess the cost effectiveness of drugs.²¹

Conclusion

Over the past 20 years the independence of drug regulation in Europe from the interests of the pharmaceutical industry has been severely threatened. This is of major concern because doctors and patients need to be able to rely on the commitment of the regulatory system in their country to put the interests of public health above the commercial interests of industry.

Funding: None.

Competing interests: None declared.

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Commentary: Concern over drug industry's influence on regulatory policy in Europe

Danielle Bardelay, Christophe Kopp

Representatives of patient groups, health professional bodies, mutual insurance systems, and consumer organisations from some 10 countries of the European Union have grouped together under the umbrella organisation Medicines in Europe Forum to campaign against the deterioration of European drug regulation that John Abraham so aptly describes.^{1,2}

Drug regulation has gradually moved away from its public health mission. National medicines agencies and the European agency are now serving first and foremost the pharmaceutical companies, who provide their main funds. So far, independent organisations of patients and health professionals in most European Union countries have either been almost ignored or patronised by regulators.

In this context the current revision of the directive and regulation on human medicines is a source for concern. Overall, the drafts are in favour of drug companies, and it is not surprising that the pharmaceutical industry has jumped at the revision, in the hope of making the legislation even more flexible and favourable to short term competitiveness. The fact that a trade oriented directorate of the European Commission, instead of the health directorate, is in charge of EU drug policy probably explains why public health interests are overlooked.³

A healthy debate is under way in the EU parliament, fuelled by amendments coming from outside the industry. Some members of the European parliament (MEPs) have realised the threats. These include shortening of drug evaluation without regular and well conducted reassessment of risks and benefits; continuing secrecy of regulatory authorities, especially regarding pharmacovigilance⁴; priority given to

industrial demands delaying generic development; and advertising direct to the consumer disguised as information.

The Committee on the Environment, Public Health, and Consumer Policy of the EU parliament has requested a delay, and voting, initially due before the summer, has been postponed to this autumn. More than 500 amendments were tabled, many of them favouring public health and patients' interests. Members of the Medicines in Europe Forum met with MEPs. Thousands of petitions, many from readers of *La Revue Prescrire*, were sent to MEPs, and around 2500 have recently been addressed to the president of the EU parliament. German independent drug bulletins have jointly expressed concerns over the commission's proposals. Members of the licensing committee (the Committee for Proprietary Medical Products) have voiced similar concerns to the president of the EU parliament.⁵

The drafts have to undergo the complex co-decision process involving the European parliament and the Council of Europe. Health ministers of member states are in charge of the drafts—these are not, as was initially feared, solely in the hands of ministers of industry. The health ministers seem divided on the issue of procedures for authorising marketing, and on the respective roles of the European and national agencies, but they are aware of the detrimental effects of direct to consumer advertising. Some ministers are under public pressure to ensure the financial independence and accountability of their regulatory authorities. A number of proposals in the directive are, however, so controversial that the discussion will go on at least until mid-2003 or 2004.

La revue Prescrire, BP459, 75527 Paris cedex 11, France

Danielle Bardelay
staff editor

Christophe Kopp
staff editor

Correspondence to:
Christophe.Kopp@wanadoo.fr

One thing is clear: the public health needs of the European Union can no longer be neglected and the regulatory agencies cannot be left to operate largely for the benefit of the drug industry. Policy makers are now aware that the revision of the pharmaceutical legislation may have enormous consequences in terms of quality of drug evaluation and health expenditure.⁶ This is an encouraging result for those who strive to publicise such little known but socially sensitive issues.

Competing interests: None declared.

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Commentary: Much ado about a good thing

J D Kleinke

191 University
Boulevard,
Suite 307, Denver,
CO, 80206,
USA
JD Kleinke
medical economist
jdklx@sprintmail.com

John Abraham's argument that the European drug regulatory community has become aligned with the commercial interests of the pharmaceutical industry invites an obvious question: so what?

During the period in which this alignment emerged and the regulatory process in the European Union became more efficient, the time required for the review of a drug's efficacy data by the United Kingdom Medicines Control Agency decreased from 154 working days in 1989 to 44 in 1998.¹ Drug approval times in the United States fell during the same period, affecting the two most critical stages of drug development and evaluation. Between 1989 and 1998, the average time required to advance new chemical entities—which represent truly breakthrough rather than “me-too” drugs—from the investigative stage to broader clinical evaluation fell from 76.0 to 70.3 months, and the subsequent average time to full market approval fell from 34.4 to 16.8 months.

One of the clearly intended consequences of this growing “problem” is the rapid increase in the number of new chemical entities and other new drugs finding their way onto the market and into patients. During the period studied by Abraham, the mean number of new chemical entities approved by the US Food and Drug Administration, for either expanded clinical evaluation or market launch, increased from 18 to 37 per year. The mean number of all new drugs approved—new chemical entities plus “me-too” drugs—increased from 63 in 1991 to 98 in 2000 (FDA data).

Has this regulatory efficiency and its consequent gush of new drugs, sparked by the alignment of the approval process with commercial interests, put patients and the public health at risk? The data argue that it has not. During the 1990s, the total number of drugs withdrawn from the US market because of concerns about patient safety remained constant, in the range of one to three a year. Between 1984 and 1988, long before the adoption of the regulatory reforms outlined in Abraham's article, 3.5% of newly approved drugs were withdrawn from the US market because of concerns about safety; between 1994 and 1998, as the regulatory process changed in ways decried by Abraham, this number decreased to 1.2%.² This decrease is good news for the public health that Abraham's paper purports to protect.

Abraham argues that disproportionately less testing of older drugs “grandfathered” on to the market further betrays a regulatory process beholden to commercial interests. Again, an obvious response to this “regulatory lapse” should be a collective shrug. The best way to wean doctors off prescribing older, ineffective drugs is not through expensive proof—via scarce regulatory resources—of what is usually clinically obvious, but through even more rapid release of newer and better drugs.

Finally, the mechanisms by which the European Union is achieving regulatory harmonisation are clearly creating “competition” among nations to become more efficient regulators of new drugs, a situation Abraham bemoans. The enlightened segments of the US healthcare community would welcome such a “problem.”

Competing interests: JDK has received honoraria, grants, and consulting fees from several pharmaceutical companies based in the United States for providing economic, business, and policy consulting services, and for providing educational services to US physician groups.

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Endpiece

Swearin'

Swearin' belongs to some thrades—like printin', bricklayin' an' plumbin'. It is no help at all, at all to tailors, shoemakers, hair-dressers, dintists, or authors. A surgeon needs it but a doctor niver.

“Swearing” in *Observations by Mr Dooley* by Finley Peter Dunne, 1902. Published by Penguin in *Words on Words* by David Crystal and Hilary Crystal

Submitted by J G Fairer, retired consultant anaesthetist, St Jean D'Angely, France

Commentary: The freedom of informed choice

Emma Bennion

John Abraham argues that regulation of new drugs should be dictated less by the desires of the pharmaceutical industry and more by the needs of patients. I have Parkinson's disease, and the drug I need has suffered at the hands of the regulators.

In the United Kingdom one in seven people who are given a diagnosis of Parkinson's disease is under 40. I found it inconceivable that I should be one of them. In 1987, aged 37, I learned that to keep me mobile I would have to rely on drugs for the rest of my life. Silently and stealthily this insidious, progressive disease has taken over. Some days I blunder through my "off" periods in a fog, trying to finish whatever I had started a few moments previously. Tasmar (tolcapone), launched in Britain in 1997, relieves the "on/off" state in Parkinson's disease and subsequently improves mobility and function.¹ To those of us prepared to put up with monthly liver function tests, this drug was a lifesaver. Instantly, my "off" periods were dramatically reduced and the rigidity and bradykinesia, so typical of young onset Parkinson's, disappeared.

But Tasmar was withdrawn in Europe in 1998 after a few reports of severe hepatotoxicity. How does this compare, for example, with the number of strokes among women taking the contraceptive pill? Quality of life for me and many other people with Parkinson's was shattered. There were days when I would just sit there, fighting back the tears, remembering how easy it used to be to walk across the room or pick up something that I had dropped, and feeling bitter at the European drug regulators.

But a few of us who can afford to do so choose to obtain Tasmar privately, and import it on prescription from the United States, at a personal cost of approximately \$700 (£450; €715) every three months. Most do not have this choice.

Healthcare professionals and policy makers need to understand that their own perceptions of health may differ from those of their patients.³ Patients need to become empowered—to take control of their illness and so ensure that it does not impair their quality of life. Patients have knowledge and experience—and a desire to manage their own condition—and these three factors should be harnessed to ensure that resources are used wisely and services provided appropriately.

Patients with long term conditions should have the right to make informed choices on issues such as whether or not to take part in drug trials, and on the pros and cons of a particular treatment and its adverse effects. I have exercised my right and have made an informed choice, even though drug regulation has left me with a barely tolerable financial burden. This is a price I am prepared to pay to remain mobile and out of residential care.

Competing interests: None declared.

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Church Farm,
Bircham Newton,
King's Lynn,
Norfolk PE31 6QZ
Emma Bennion
patient
bennion@paston.
co.uk

A memorable patient

Straight from the patient's mouth

He was a 45 year old unemployed man living in a lower middle class joint family home in an urban area. He was referred for psychiatric evaluation by a private practitioner because he was depressed and irritable, he complained of sleep disturbance, and he described a constant clicking sound arising from the middle of his head. The last mentioned symptom evoked much interest, and I, the then junior resident in the unit, was instructed to present this unusual patient at the clinical psychiatry rounds. Patients with psychiatric problems do not always tell their story well, and clinicians often need to draw on their experience to find coherent strands in a narrative. Thus, my fellow residents understandably saw in this patient what they had been accustomed to in previous patients. The consensus was that he was phenomenologically experiencing elementary extracampine auditory hallucinations, and that his irritability and mood disturbance were perhaps epiphenomena of a paranoid illness, the symptoms of which I had failed to successfully elicit. I, however, had an ace up my sleeve. Unknown to my colleagues, during my exchange with the patient, I had asked, "Can other people hear the clicking that you hear inside your head?" "I suppose so," he replied, a little doubtfully. "I'd need to open my mouth, and they'd need to put their ears really close up."

"Open your mouth," I suggested. The patient opened wide, and I thrust my ear next to his mouth. Surprise—I, too, heard the clicking sound.

The patient had palatal myoclonus. This was the reason for his poor sleeping; and his insomnia, and the disbelief that his symptom evoked in all and sundry, were doubtless responsible for his irritability and depression.

Nearly 20 years have passed, but I have never forgotten the lesson: that I should always listen to my patients and test the goodness of fit of their beliefs before I try to fit them into my scheme of the universe.

Chittaranjan Andrade additional professor, department of psychopharmacology, National Institute of Mental Health and Neurosciences, Bangalore, India

We welcome articles up to 600 words on topics such as A memorable patient, A paper that changed my practice, My most unfortunate mistake, or any other piece conveying instruction, pathos, or humour. If possible the article should be supplied on a disk. Permission is needed from the patient or a relative if an identifiable patient is referred to.