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The stock market, first served

The stock market is driving up the cost of new drugs to unsustainable levels. But its harmful influence on public health does not end there.

Financial markets informed before drug regulatory agencies. In the United States, in the spring of 2015, the Food and Drug Administration (FDA) criticised the company Orexigen Therapeutics for publicly releasing the results of the interim analysis of its ongoing trial of Mysimba® (*bupropion* + *naltrexone*) to the Securities and Exchange Commission (SEC), the US agency that oversees the stock market (1). The FDA had required this trial, and this disclosure compromised the trial's integrity (1,2).

In Germany, the authority responsible for health technology assessments (G-BA) criticised the drug company Chiesi for sending information to the SEC about the gene therapy product *alipogene tiparvovec*: the G-BA obtained this information, which could have influenced its decision concerning the product, from the SEC rather than from Chiesi (3).

In both cases, the SEC, and thus financial markets, were the first to be informed by the company about data on the drug's harm-benefit balance.

In the US, the "revolutionary" diagnostic tests of the company Theranos were advertised

directly to the public, without prior publication in the scientific literature (4).

For these companies, run by engineers and entrepreneurs, there is a great temptation to announce their products in the mass media and financial press rather than submit their results to scientific journals (4).

Regulatory scrutiny should come first. These cases once again demonstrate the powerful influence of financial interests in the biomedical field.

The requirements and controls that are in place in the pharmaceutical sector were introduced in response to public health disasters. These advances are fragile and sometimes openly challenged (5,6).

Patients, healthcare professionals and health authorities must vigorously defend scrutiny of the pharmaceuticals market by regulators, against the pervasive greed among those who obtain all or part of their income from financial markets.

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Selected references from Prescrire's literature search.

- 1- Husten L "Orexigen released interim data without approval of trial leaders" *Forbes* 3 March 2015. www.forbes.com accessed 24 June 2015: 11 pages.
- 2- Prescrire Rédaction "Gâchis" *Rev Prescrire* 2015; **35** (380): 411.
- 3- "German HTA slams cagey Chiesi Glybera disclosure" *Scrip* 2015; (3748): 1-6.
- 4- Ioannidis JPA "Stealth research. Is biomedical innovation happening outside the peer-reviewed literature?" *JAMA* 2015; **313** (7): 663-664.
- 5- Singer M et al. "L'Europe n'est pas prête pour l'innovation médicale" *Le Monde* 29 May 2015: 1 page.
- 6- Montastruc JL and Toussaint B "Médicaments innovants: jusqu'où laisser aller les apprentis sorciers?" *Le Monde* 16 June 2015: 1 page.