

Communication with sales representatives

the traps we should avoid

What is a Medical Representative?

A medical representative is above all a provider of information to make doctors and other medical professionals more knowledgeable. Medical reps bring new products, devices, and drugs designed to cure and aid a multitude of illnesses and ailments. Without medical reps, doctors would not become aware of new advancements in treatments, more effective drugs, and devices that provide enhanced treatment opportunities.

<http://www.medicalrepresentative.net/>

Medical Representative Job Description

Medical reps are usual assigned a geographical territory in which they operate. This can be as small as a few city blocks and as large as a country. Most territories are sized so that you can drive to most of your sales locations in less than a day.

Medical Representative Job Description

- Develop and manage an assigned territory with the goal of maximizing sales
- Achieve quarterly and annual sales goals
- Meet target call goals with a focus on top customers
- Host product presentations to designated customers
- Understand and address both business and scientific needs of healthcare professionals
- Engage in meaningful dialogue with customers

Promotional Activities of Industry and Work of Medical Representatives in Latvia

- Working at spot - pharmacies, hospitals, outpatient-clinics and FD/GP practices
- Free samples for practice
- Continuing medical education - be aware : are you getting educated or brain washed?
- Support of participation in conferences and congresses.

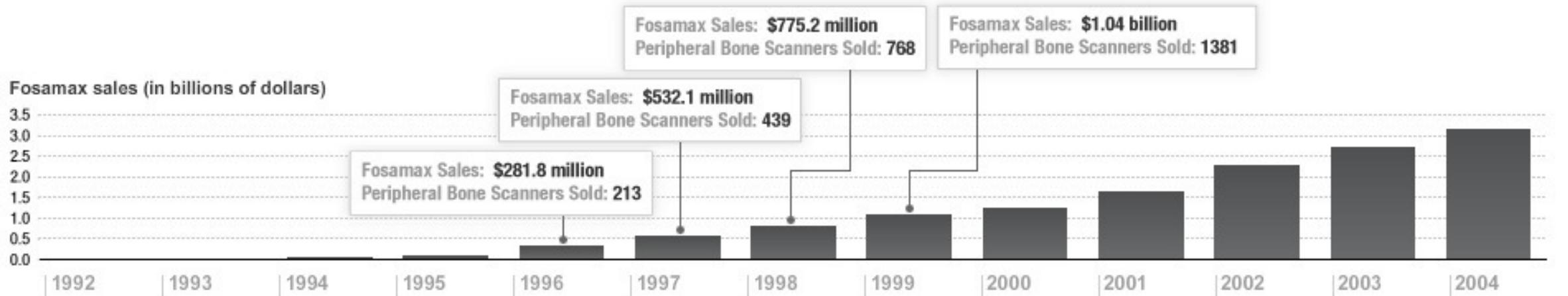
Disease mongering

The process of widening the boundaries that define medical illness in order to expand markets for those who deliver and sell treatments

Illich I. Limits to medicine. London: Penguin; 1990.
Payer L. Disease-mongers. New York: John Wiley; 1992

Fosamax 1995

- Alendronic acid (bisphosphonate drug)



<http://www.npr.org/2009/12/21/121609815/how-a-bone-disease-grew-to-fit-the-prescription>

Diagnostic criteria

- 1992 WHO & osteoporosis expert meeting in Rome
- The question for experts was this:
Since after the age of 30 all bones lose density, how much bone loss was normal?
- Established criteria for osteoporosis and osteopenia



<http://www.npr.org/2009/12/21/121609815/how-a-bone-disease-grew-to-fit-the-prescription>

Moynihan, R. & Cassels, A. (2005). *Selling Sickness: how the world's biggest pharmaceutical companies are turning us all into patients*. Vancouver: Greystone.

Diagnostic criteria (II)

«Over a two- or three-day period the experts in the room went back and forth and back and forth, looking at research and trying to decide precisely where on a graph of diminishing bone density to draw a line. Ultimately it was just a matter of, 'Well ... it has to be drawn somewhere. And as I recall, it was very hot in the meeting room, and people were in shirt sleeves and, you know, it was time to kind of move on, if you will. And, I can't quite frankly remember who it was who stood up and drew the picture and said, 'Well, let's just do this.'»

Anna Tosteson, a professor of Dartmouth Medical School

<http://www.npr.org/2009/12/21/121609815/how-a-bone-disease-grew-to-fit-the-prescription>

Diagnostic criteria (III)

- Criteria widely accepted, but remain controversial
- «Normal» - bone density of a young white female
- The link between bone density and fracture risk is also the subject of scientific controversy
- The meeting was sponsored by the pharmaceutical industry

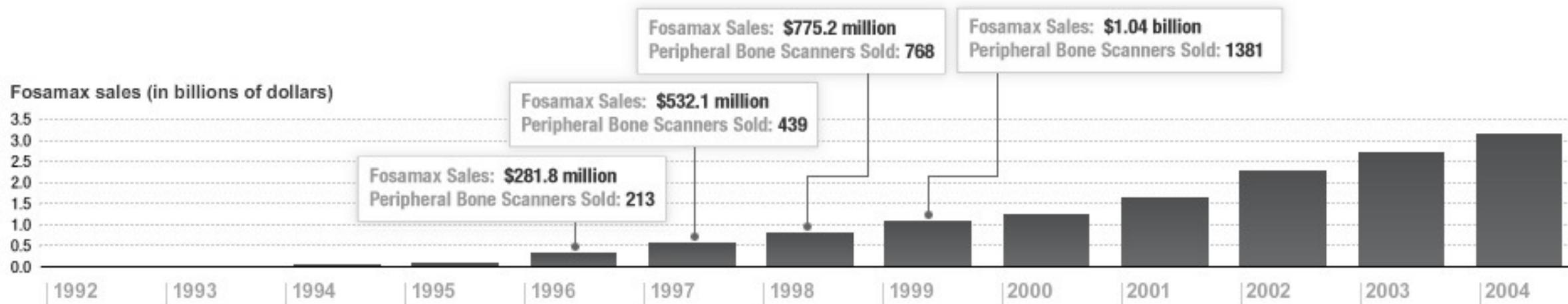
Green C, Bassett K, Foerster V, Kazanjian A. (1997). Bone mineral density testing: does the evidence support its selective use in well women? Vancouver, BC: British Columbia Office of Health Technology Assessment;
Moynihan R, Heath I, Henry D. (2002). Selling sickness: the pharmaceutical industry and disease mongering. *BMJ*. Apr 13;324(7342):886-91.

Measuring bone density

- In 90s large bone densitometers were used - exams expensive
- 1995 Merck established Bone Measurement Institute
- Eventually purchased densitometer business and produced peripheral machines
- Through sales reps doctors were introduced to these machines and diagnosis of osteoporosis
- Merck also developed a leasing program



<http://www.npr.org/2009/12/21/121609815/how-a-bone-disease-grew-to-fit-the-prescription>



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* The project benefits from a grant from Iceland, Liechtenstein and Norway through the EEA Grants.

Disease awareness

«Basically the average person in the street wasn't really all that worried about it. In fact, in the early 1990s, few people had even heard about osteoporosis and if they had, it was largely dismissed as something hunched over little old ladies had»

Kym White, PR specialist at Ogilvy Public Relations

Moynihan, R. & Cassels, A. (2005). *Selling Sickness: how the world's biggest pharmaceutical companies are turning us all into patients*. Vancouver: Greystone.

Disease awareness (II)

- Funding patient organizations
- Educating public about the disease

<https://www.youtube.com/watch?v=amWbHTWU0Ww>

<https://www.youtube.com/watch?v=xdOCmpS6cX4>

- Public meetings with experts
- Lobbying in the governments around the world
- Number of bone density tests done in the province of Alberta went from around 13 000 in 1996 to over 90 000 by the year 2000



Moynihan, R. & Cassels, A. (2005). *Selling Sickness: how the world's biggest pharmaceutical companies are turning us all into patients*. Vancouver: Greystone.

Madeleine Albright

- Prominent American diplomat and politician
- Visited Latvia in 2004 to advocate for the reimbursement of osteoporosis treatment
- Visit was sponsored by Merck



Expanding the market: osteopenia

- Women who are «at risk of being at risk»
- Drugs advertised for prevention
- In 2003 Merck's market research report showed that in the US about 8 million women had been found to have osteopenia and about a third of them were taking an osteoporosis drug
- Studies have shown that the benefits of osteoporosis drugs may be marginal. Approximately 270 women with osteopenia might need to be treated with drugs for three years so that one of them could avoid a single vertebral fracture

Alonso-Coello P, García-Franco AL, Guyatt G, Moynihan R (2008). Drugs for pre-osteoporosis: prevention or disease mongering? *BMJ* 336 (7636): 126-9.
Cummings SR, Black M, Thompson DE, Applegate WB (1998). Effect of alendronate on risk of fracture in women with low bone density but without vertebral fractures: results from the fracture intervention trial. *JAMA*.280:2077-2082.

The risk of disease mongering

- Person's loss of bone density only contributes about one-sixth of their overall risk of a future hip fracture, and that several other factors such as the strength of muscles and likelihood of falling have a big influence
- Slowing the loss of bone density with drugs can help reduce the risk of a hip fracture, but it is just one factor and it only makes a limited contribution
- Many ways to prevent a fracture - lifestyle, diet, house arrangements
- The focus on bone density measurements and drugs divert us from applying other cost-effective solutions

Marshall D, Johnell O, Wedel H. (1996). Meta-analysis of how well measures of bone mineral density predict occurrence of osteoporotic fractures. *BMJ*;312:1254-9.

Schousboe JT, Nyman JA, Kane RL, Ensrud KE. (2005). Cost-effectiveness of alendronate therapy for osteopenic postmenopausal women. *Ann Intern Med*;142:734-41.

Therapeutics Initiative (2011). A Systematic Review of the Harms of Bisphosphonates Therapeutics Letter Issue 84 / NOV - DEC [HTTP://WWW.TI.UBC.CA/LETTER84](http://www.ti.ubc.ca/letter84)

Therapeutics Initiative (2011). A Systematic Review of the Efficacy of Bisphosphonates THERAPEUTICS LETTER ISSUE 83 / SEP - OCT [HTTP://WWW.TI.UBC.CA/LETTER83](http://www.ti.ubc.ca/letter83)

Promotion and Use of Off-label Pharmaceuticals in Europe

- There is very little regulation of off-label pharmaceutical use on an EU-wide basis.
- There is no legal definition of ‘off-label use’ at the EU level.
- Promoting the prescription of a pharmaceutical product for a purpose that has not been approved is prohibited in EU.

Promotion and Use of Off-label Pharmaceuticals in Europe

- Whether or not physicians are allowed to prescribe pharmaceuticals on an off-label basis depends on the laws of the individual Member States.
- In some cases, physicians are not only permitted to prescribe off-label drugs, they are required to do so in order to avoid malpractice claims by patients .

Promotion and Use of Off-label Pharmaceuticals in Europe

- Before prescribing off-label uses, physicians must provide patients with comprehensive information about the drug:
- it is not approved for the proposed use in that patient,
- the risks associated with its use are unknown
- it may not be reimbursed.

Failure to do so may entitle patients to bring damages claims .

Promotion and Use of Off-label Pharmaceuticals in Europe

- Manufacturers who are found to have improperly promoted off-label drug use face serious potential consequences in the EU.
- In Germany for example, healthcare supervisory authorities may impose administrative fines of up to €50,000 per incident.
Although they have only done so very rarely.

Promotion and Use of Off-label Pharmaceuticals in USA

- US laws and regulations do not directly regulate the prescription of medicines by physicians.
- Physicians are expected to use their medical judgment, acting in the best interests of the patient, in pre- scribing medications.
- Provided physicians are well informed about the product and have a credible clinical justification, they may prescribe any drug product approved by the US Food and Drug Administration (FDA), including for off-label uses.

Promotion and Use of Off-label Pharmaceuticals in USA

- Drug manufacturers are prohibited from marketing or promoting off-label uses of their products to induce commercial sales.
- Once the FDA has approved a product as safe and effective for a specified use, promotion for other uses not specified in an FDA-approved label may result in ‘misbranding’ which is prohibited by legislation.

Promotion and Use of Off-label Pharmaceuticals in USA

- The law does not prohibit the exchange or dissemination of truthful and non-misleading information about a product's unapproved uses in specific circumstances.
- Tension remains in the law between the government's goal of regulating off-label promotion and a company's constitutional right to disseminate truthful, non-misleading information about off-label uses.

Examples for Off-label Promotion

- The 2006 study examined 84 published studies on atypical antipsychotic medicines (olanzepine, risperidone, quetiapine).
- Most common off-label uses were for treatment of depression, obsessive-compulsive disorder (OCD), post-traumatic stress disorder (PTSD), personality disorders, Tourette's syndrome, autism, and agitation in dementia.
- It concluded that with few exceptions, there was insufficient high-strength evidence to reach conclusions about the efficacy of any off-label uses of these medications.
- It also found strong evidence that atypical antipsychotics are associated with increased risk of adverse events such as significant weight gain, sedation, and, among the elderly, increased mortality. Future research areas were suggested.

Examples for Off-label Promotion

- Ondansetron – Hyperemesis is a common unlabeled indication for use of Ondansetron 4 to 8 mg can be taken orally every eight hours, as needed, or administered intravenously by bolus injection every eight hours, as needed.
- A single report described use of subcutaneous ondansetron via a microinfusion pump in 521 women with severe nausea and vomiting, with improvement of symptoms to mild to moderate in 50 percent of women within three days of therapy .
- Based on this report and data in other populations, administration of ondansetron via a microinfusion pump appears to be a reasonable alternative route for treating severe nausea and vomiting of pregnancy.

Examples for Off-label Promotion

- Most common medicines-related side effects -headache, fatigue, constipation, and drowsiness
- Less-common medicines-related side effects : QT prolongation, particularly in patients with underlying heart conditions, such as congenital long QT syndrome; patients with hypokalemia or hypomagnesemia.

ECG monitoring is recommended in these patients.

Examples for Off-label Promotion

- Animal data on ondansetron are reassuring as to its safety in pregnancy.
- Human data on safety or efficacy of ondansetron for treatment of hyperemesis are based on case reports, small series, and a historical cohort of 1849 women in Denmark exposed during pregnancy .
- In record linkage study (1233 first trimester exposures), ondansetron was not associated with an increased risk of major congenital anomalies, miscarriage, low birth weight, or small for gestational age when used for treatment of nausea and vomiting of pregnancy .
- Another study using the same database reported an association between filling a prescription for ondansetron during the first trimester of pregnancy and heart defects in the offspring, these data have only been presented in abstract form and cannot be adequately evaluated.