MED SHADOW | Balancing the risks & benefits of medicines

BISPHOSPHONATES:

Benefits, Risks, and Patient Protections

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SIDE EFFECTS

MED SHADOW | Balancing the risks & benefits of medicines

25% of all new drugs

have black box or significant warnings within 5 years.

How to Update a Drug Label:

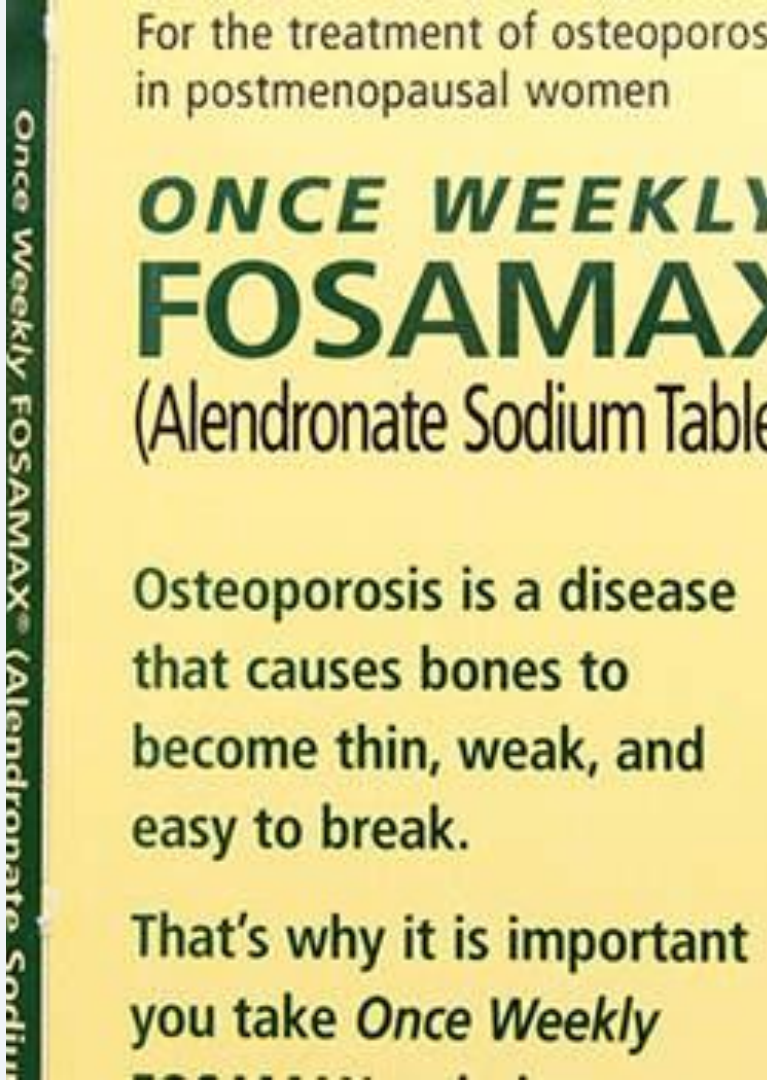
Changes Being Effected, FDA reviews changes after they are made

Alternatively:
Prior Approval Supplement (PAS) request to FDA for a label change. Then required to wait for FDA approval.

FDA approves or sends a Complete Response Letter

Fosamax approved in 1995 for osteoporosis in postmenopausal women.

No label requirement for femoral fractures.



Of the estimated 10 million Americans with osteoporosis, about eight million are women.

A woman’s risk of breaking a hip is equal to her combined risk of breast, uterine and ovarian cancer.

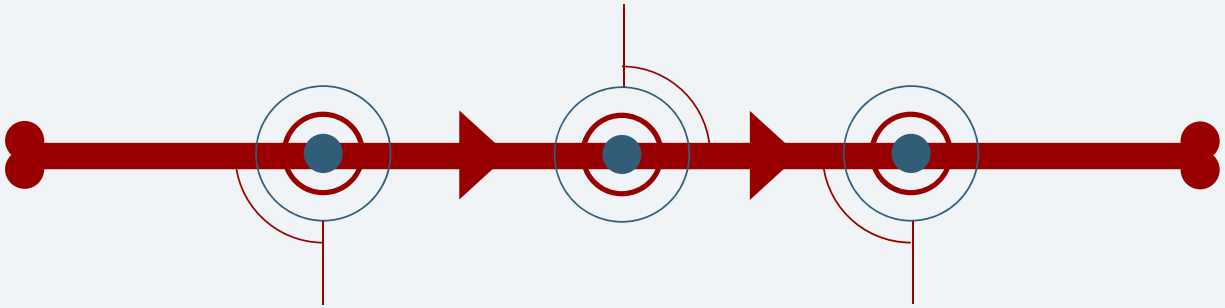
Approximately one in two women over age 50 will break a bone because of osteoporosis.

About half the people who have a hip fractures aren't able to regain their ability to live independently. (Mayo Clinic)

How does Fosamax work?

(2)

Increases bone mineral density



(1)

Slows resorption which is the breakdown phase of normal bone remodeling

RESULT

Significantly reduces the risk of spine, hip, and wrist fractures in women with osteoporosis.

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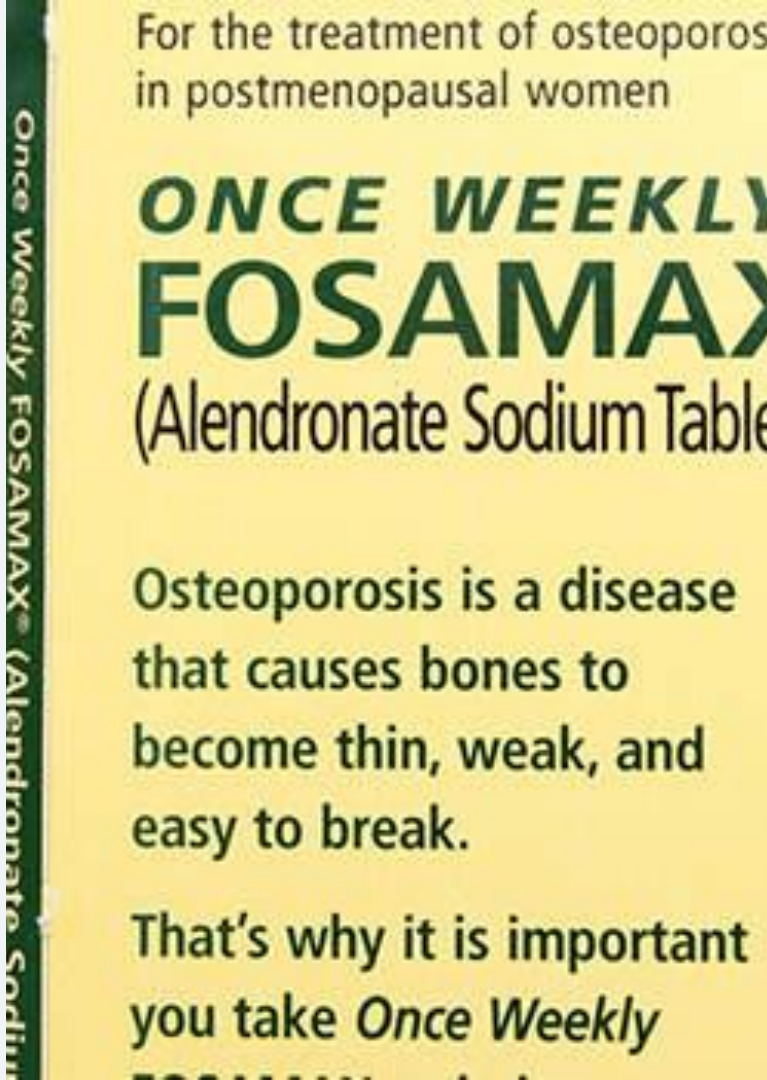
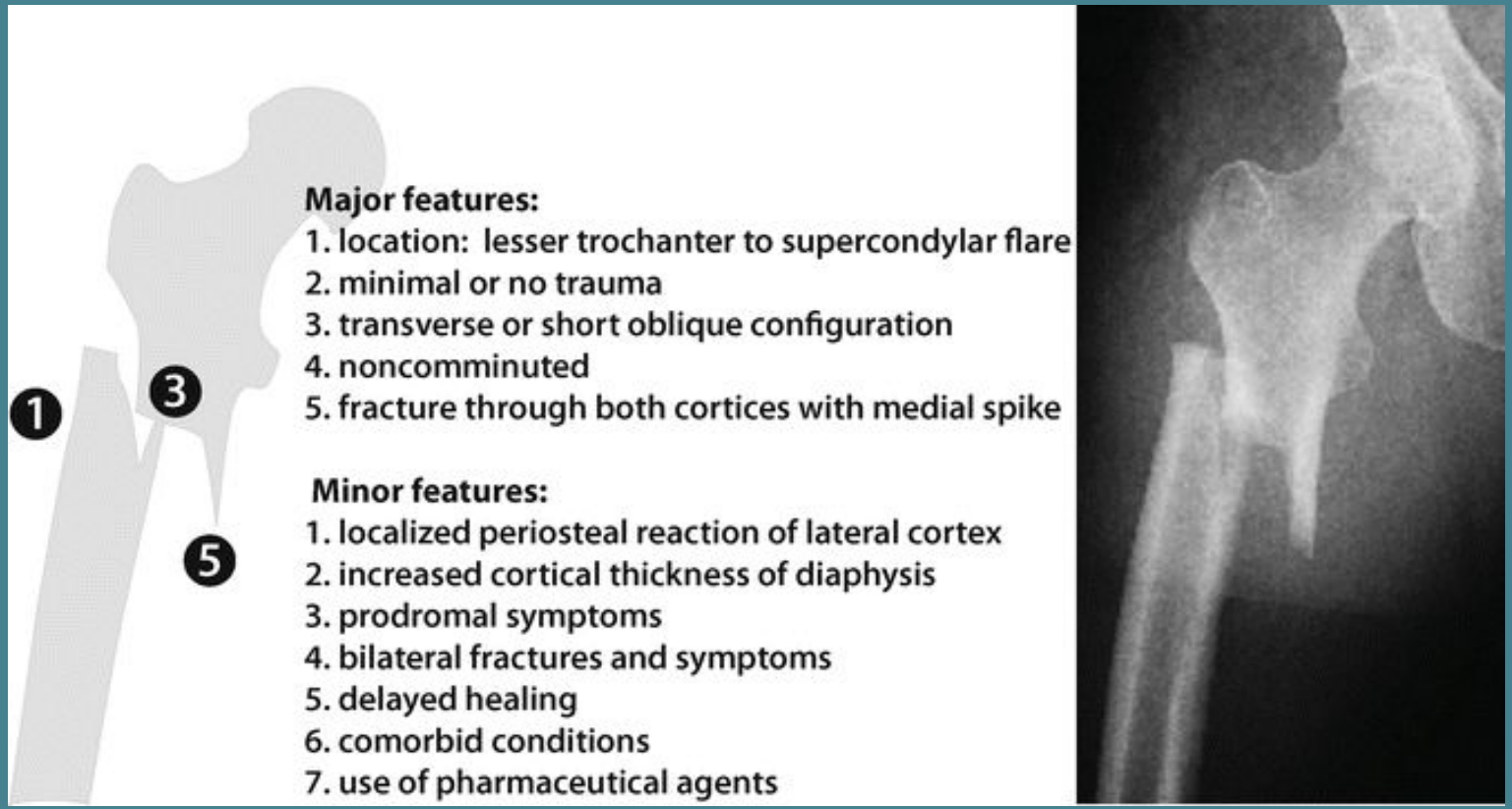
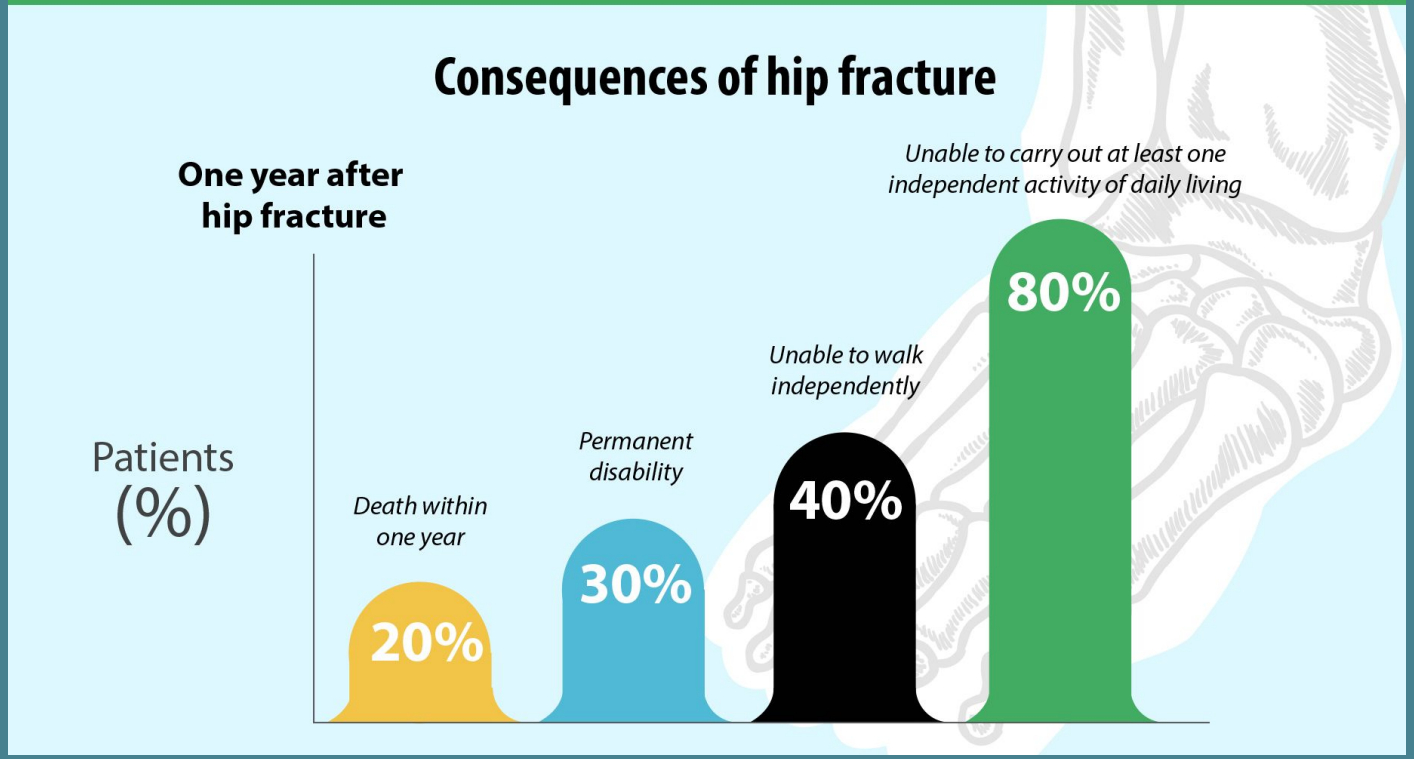
1997 Fosamax approved for the *prevention* of osteoporosis



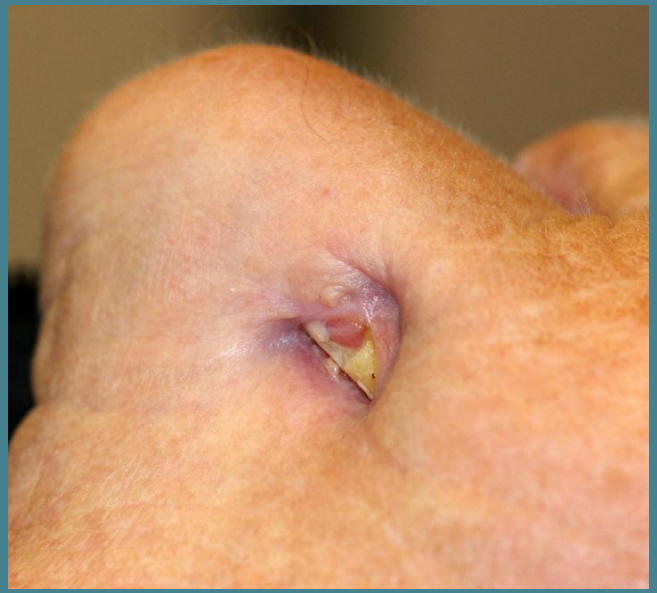


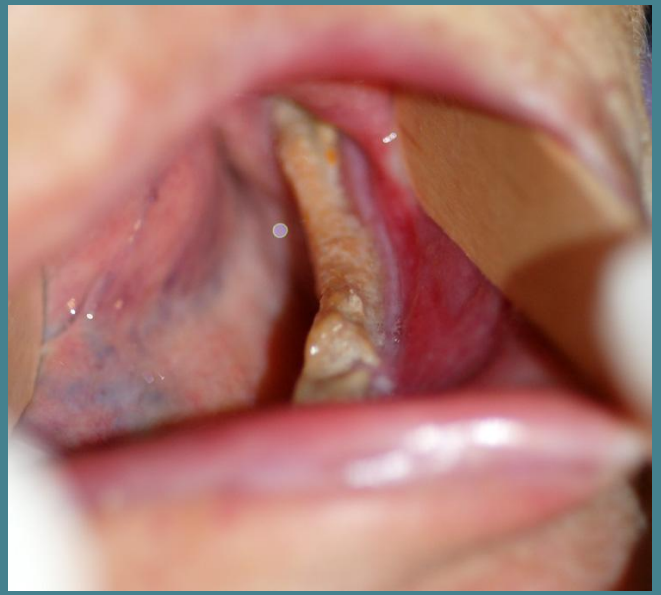
Source: SpringerLink

Hip fractures can actually be quite deadly



Necrosis of the jaw





How to Update a Drug Label:

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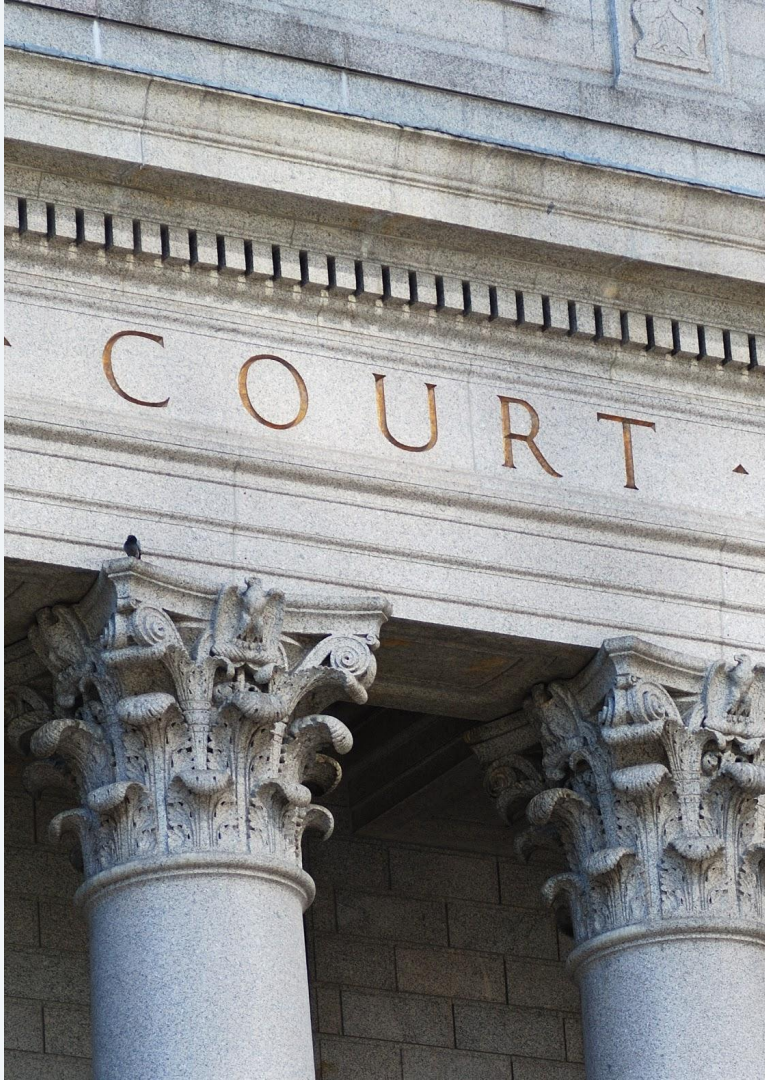
Supreme Court

Merck vs. Albrecht

500 women class action lawsuit - Fosamax fractures

Why MedShadow sponsored an Amicus Brief:

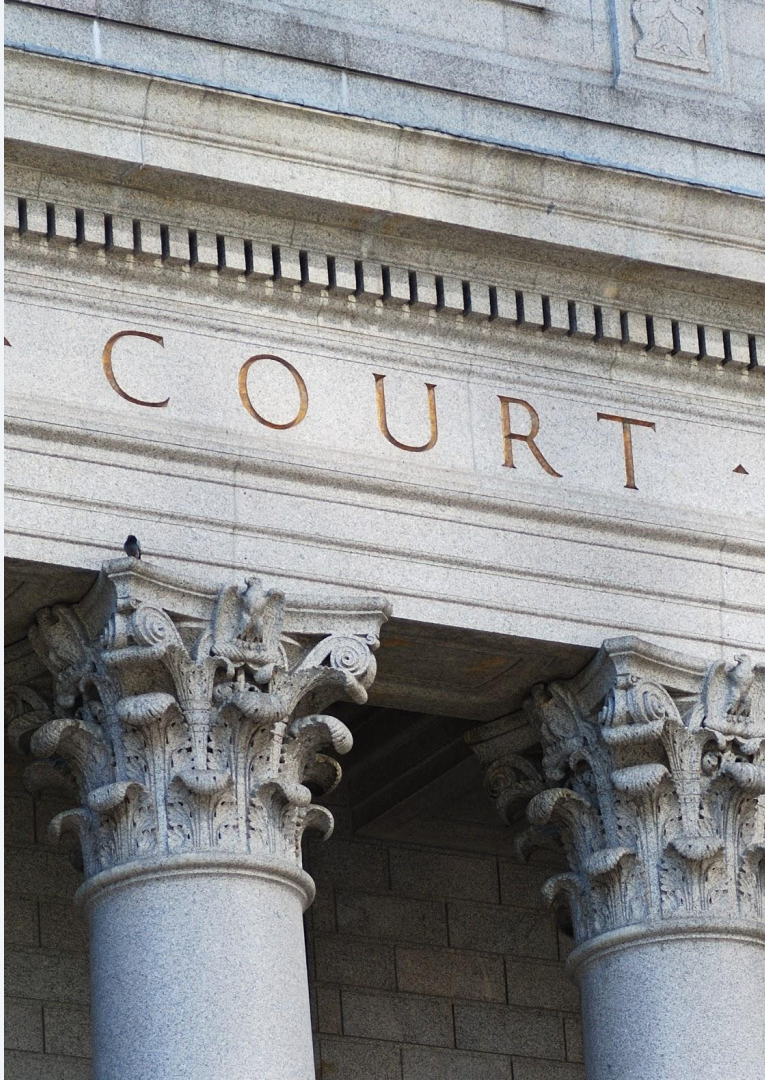
- Public's right to be warned
- Distortion of Impossibility Preemption
- Merck's actions were disingenuous
- True warning never offered, never rejected



What the Supreme Court said:

- Creates an incentive to submit weak label changes
- Rejection based on phrasing: stress fracture
- Clear evidence requires full info to FDA

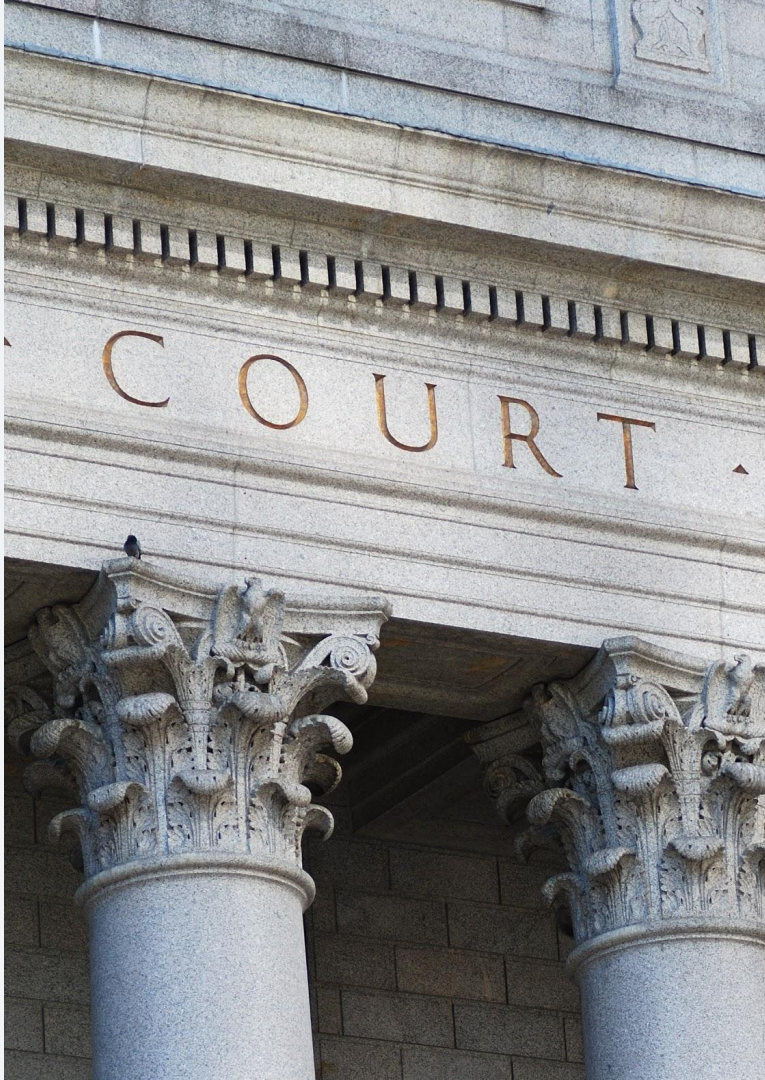
Central premise: Manufacturer bears the duty to warn



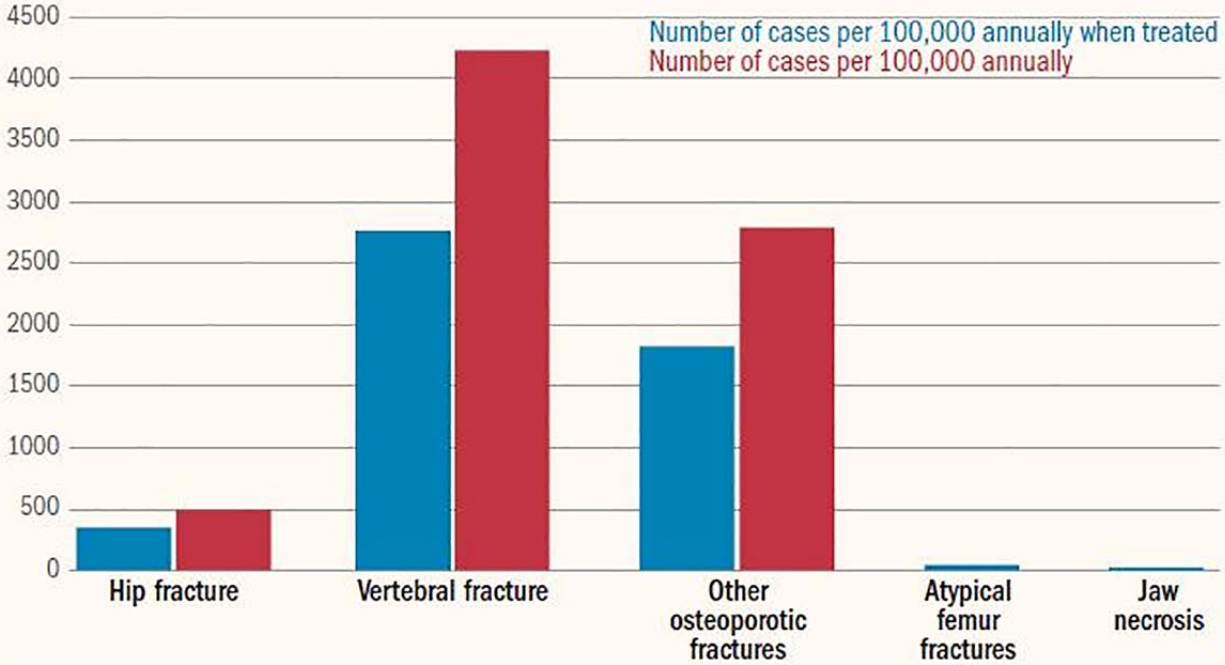
Conclusion:

Did Merck Circumvent duty to warn?

- Trigger Impossibility Clause purposely
- Block ability to sue
- Patients' right to information



Risks with and without bisphosphonate therapy



Source: Adapted from Adler RA et al. "Managing osteoporosis patients after long-term bisphosphonate treatment." *Journal of Bone and Mineral Research* (Jan. 2016), Vol. 31, No. 1, pp. 16–35.

THANKS!

Does anyone have any questions?

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