

Celebrating Baruch

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Disclosures

We love Baruch

He changed our lives

Teachers

Researchers

People

Date: 08 Sep 95 16:34:59 EDT

From: Steven Woloshin

Subject: Re: Mammography Grant

To: bf0r+@andrew.cmu.edu

We (Lisa Schwartz and I) are hard working, eager 2nd year fellows. We trained as general internists and worked for a few years as full time clinicians. For the past 2 years we have been doing a fellowship in outcomes research and we're getting Dartmouth's version of an MPH.

We're very excited about this project - and we're especially excited about having the chance to work with you.

Steve & Lisa

Date: Fri, 8 Sep 1995 17:04:30 -0400 (EDT)

From: Baruch Fischhoff bf0r+@andrew.cmu.edu

Subject: Re: Mammography Grant

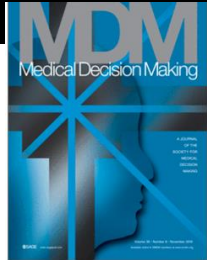
I have read the draft proposal quickly, but still thoroughly enough to feel that we're on the same wavelength.

You wouldn't be there (Dartmouth-Outcomes) if you weren't very good at what you do.

You wouldn't be interested in our work if you didn't have outstanding taste.

This looks like an excellent opportunity to combine our fields, let's go for it.

Baruch



Patient-Centered Decision Making

Women's Views on Breast Cancer Risk and Screening Mammography:

A Qualitative Interview Study

E. SILVERMAN, MD, MPH, MS, S. WOLOSHIN, MD, MS, L. M. SCHWARTZ, MD, MS,
S. J. BYRAM, PhD, H. G. WELCH, MD, MPH, B. FISCHHOFF, PhD

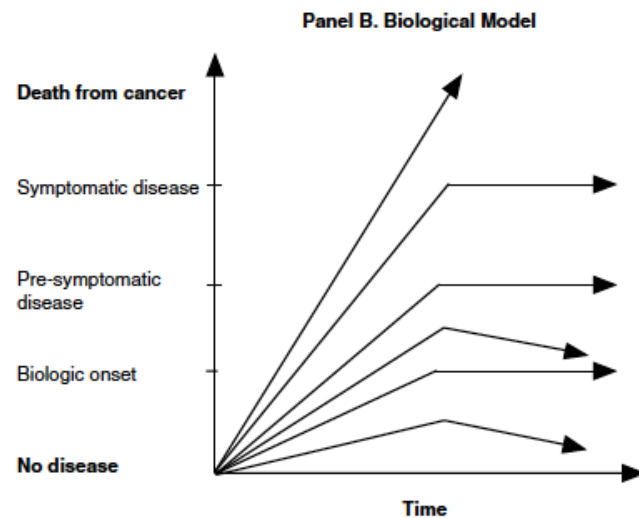
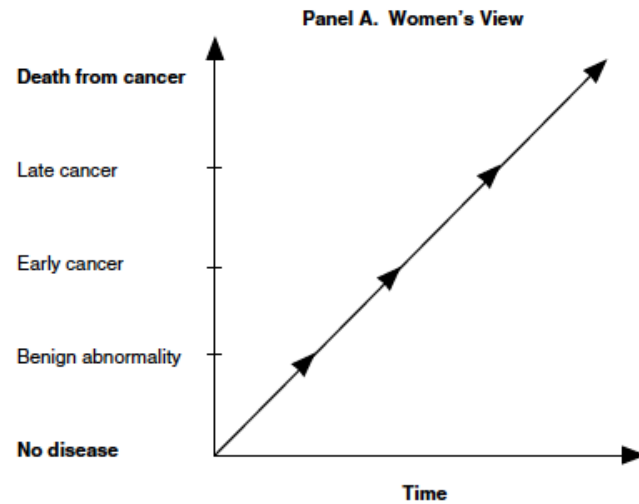


FIGURE 1. Comparison of the women's view of the natural history of breast cancer to a biological model. Women viewed breast cancer as a naturally progressive disease, some believing that even "benign" abnormalities could develop into cancer. In contrast, the biological model classifies benign disease as a separate entity and breast cancer as a heterogeneous disease, not all of which may progress.

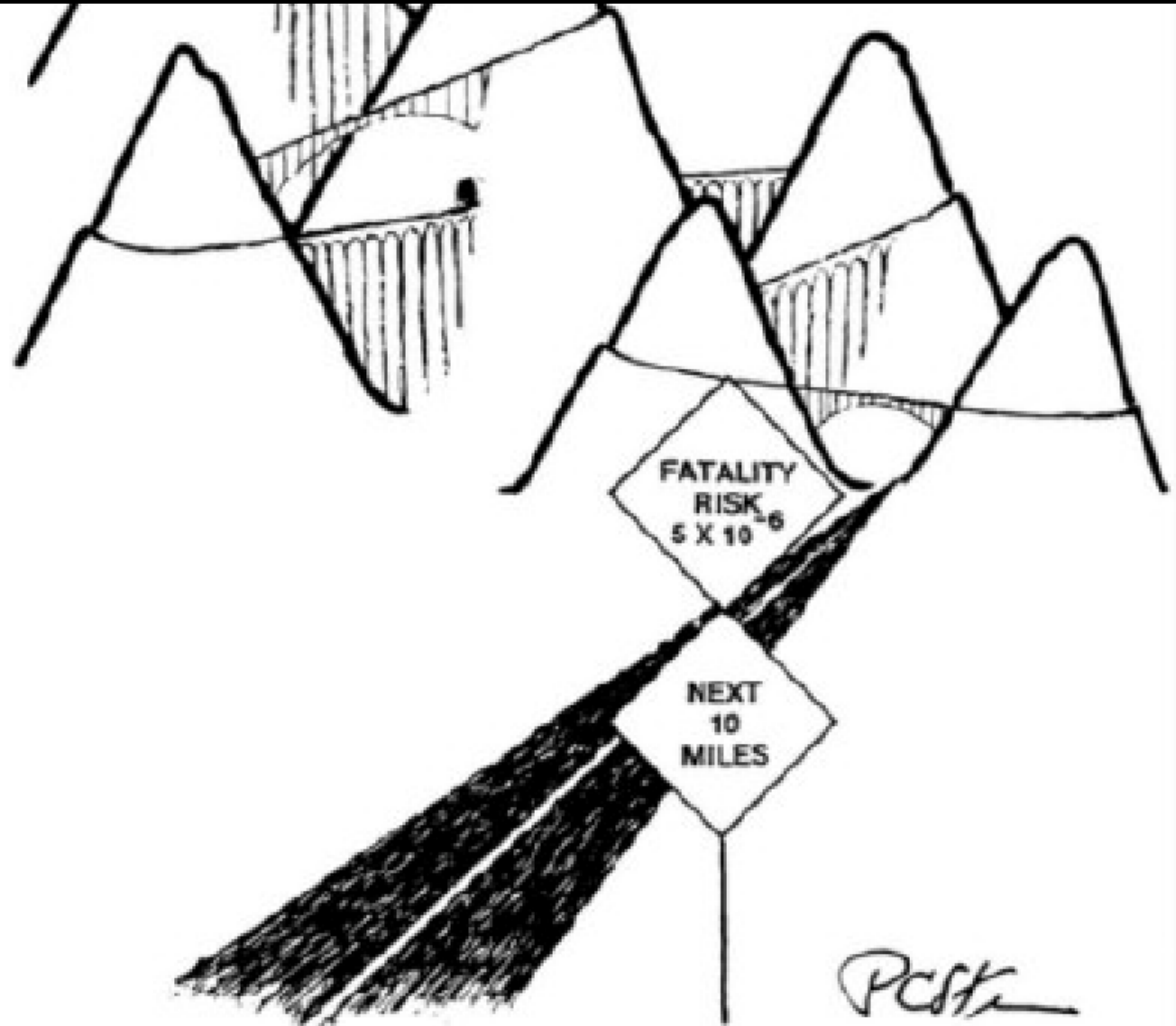


Consequences for Society

- "People are stupid" meme
- Amateurish design of vital communications
- Expert despair over seemingly incompetent public

Preventing Overdiagnosis, Sept 2016, Barcelona

"From a public health perspective, one should be no more willing to expose the public to an untested message than to an untested drug." Baruch



Lunesta

(compared to sugar pill) to reduce current symptoms for adults with insomnia

What this drug is for:

To make it easier to fall or to stay asleep

Who might consider taking it:

Adults age 18 and older with insomnia for at least 1 month

Recommended monitoring:

No blood tests, watch out for abnormal behavior

Other things to consider:

Reduce caffeine intake (especially at night), increase exercise, establish a regular bedtime, avoid daytime naps

How long has the drug been in use?

Lunesta was approved by FDA in 2005. As with all new drugs we simply don't know how its safety record will hold up over time. In general, if there are unforeseen, serious drug side effects, they emerge after the drug is on the market (when a large enough number of people have used the drug).

Lunesta Study Findings

788 healthy adults with insomnia for at least 1 month – sleeping less than 6.5 hours per night and/or taking more than 30 minutes to fall asleep – were given LUNESTA or a sugar pill nightly for 6 months. Here's what happened:

What difference did LUNESTA make?	People given a sugar pill	People given LUNESTA (3 mg each night)
Did Lunesta help?		
LUNESTA users fell asleep faster (15 minutes faster due to drug)	45 minutes to fall asleep	30 minutes to fall asleep
LUNESTA users slept longer (37 minutes longer due to drug)	5 hours 45 minutes	6 hours 22 minutes
Did Lunesta have side effects?		
Life threatening side effects:		
No difference between LUNESTA and a sugar pill	None observed	None observed
Symptom side effects:		
More had unpleasant taste in their mouth (additional 20% due to drug)	6%	26%
More had dizziness (additional 7% due to drug)	3%	10%
More had drowsiness (additional 6% due to drug)	3%	9%
More had dry mouth (additional 5% due to drug)	2%	7%
More had nausea (additional 5% due to drug)	6%	11%

Simple tabular display of benefit and side effects (serious and symptom)

Benefit-Risk Summary and Assessment

Addyi (flibanserin) is a post-synaptic 5-HT_{1A} agonist and 5-HT_{2A} antagonist, and a new molecular entity. It also binds with moderate affinity to 5-HT_{2B}, 5-HT_{2C}, and dopamine D₄ receptors. I concur with the recommendation of the Division of Bone, Reproductive and Urologic Products to approve Addyi (flibanserin) tablets for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is not due to:

- A co-existing medical or psychiatric condition,
- Problems within the relationship, or
- The effects of a medication or other drug substance

Acquired HSDD refers to HSDD that develops in a woman who previously had no problems with sexual desire. Generalized HSDD refers to HSDD that occurs regardless of the type of stimulation, situation or partner. ADDYI is not indicated for the treatment of HSDD in postmenopausal women or in men, or to enhance sexual performance. To ensure that the benefits of the drug outweigh the risks of severe hypotension and syncope when taken with alcohol, Addyi will be approved with a REMS, or risk evaluation and mitigation strategy, with elements to assure safe use.

The recommended dose of Addyi is 100 mg administered orally once per day at bedtime.

HSDD is a multi-faceted disorder that encompasses a spectrum of symptoms of varying severity. Women with HSDD experience considerable distress or anxiety over their loss of sexual desire, rarely initiate sexual contact and often avoid intimate situations. Loss of sexual desire can result in loss of self-esteem and feelings of inadequacy, isolation and guilt, and can negatively impact the woman's relationship with her partner.

There is an unmet medical need for safe and effective treatments for women with HSDD. Certain psychological interventions can improve symptom severity and sexual satisfaction in women with HSDD. There is, however, a lack of controlled trials comparing different types of psychological interventions, or that are designed to assess the contribution of medications, such as flibanserin, to psychological interventions in women with HSDD. Future methodologically sound trials of sufficient size are needed to further evaluate the efficacy of treatment options for HSDD.

There are no FDA-approved drugs for the treatment of HSDD. Some women report improvements in their symptoms with over-the-counter products, such as supplements (e.g., DHEA), or off-label prescription therapies such as various testosterone products, combination estrogen and progesterone products, and antidepressants. The benefits of these therapies have not been established and are often outweighed by their attendant side effects.

The efficacy of Addyi (flibanserin) was established in three North American randomized, placebo-controlled trials involving 2409 premenopausal women.

Take home points

How to be a real mentor

How to communicate

People are smart – respect their intelligence

If you don't want to confuse people, don't be confusing

Useful messages are hard work –TEST THEM

Thank you Baruch!