

SELLING SICKNESS → CAUSING DEATH

“Mistakes” and Solutions

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Public Citizen’s Health Research Group

December 2004 FDA Advisory Committee Meeting: Testosterone Patch to Increase Women's Sexual Desire

Dr. Tiefer and I opposed the approval of "Intrinsa" because of concerns about increased breast cancer and heart disease and other reasons:

"Decreased sexual desire is a very complicated problem, as discussed by Dr. Tiefer today. There is little question that a large proportion of women with this complaint respond very well to counseling that may reveal underlying problems such as a history of being sexually abused, current unstable or unhealthy relationships, depression or other causes better dealt with directly rather than being glossed over with a testosterone patch. **The journalist H.L. Mencken has said that for every complicated problem there is a simple solution — which is usually wrong.**"

Are there significant differences between those who illegally sell dangerous street drugs and the more “prestigious,” (sometimes) legal pharmaceutical industry?

Some differences, but the first large international pharmaceutical company, Bayer, and the street drug industry clearly have something in common: heroin.

15 years ago, in 1998, the British *Sunday Times*, marked the 100th anniversary of the commercial launch of heroin by publishing an historical summary about the company that owned the drug's brand name.

Bayer chemist Heinrich Dreser first tested the drug in animals and then on humans (Bayer employees, himself included) in 1898. As the article states, “[T]he workers loved it, some saying it made them feel ‘heroic’ (heroisch).” Thus, a brand name, HeroinTM, was born.

In November 1898, Dreser first presented Heroin™ (the trademark having been acquired in June of that year) at a medical meeting. He described it as “**10 times more effective as a cough medicine than codeine**” with “**only a tenth of its toxic effects.**” The new drug was thought to work better than morphine while at the same time being **safe and not addictive.**

Not surprisingly, Heroin™ was extraordinarily successful. Bayer sent out free samples to thousands of European and U.S. physicians and a year after Dreser's presentation, Bayer's production of the drug was about one ton per year, with exports going to 23 countries.

The country where it really took off was the U.S., where there was already a large population of morphine addicts, a craze for patent medicines, and a relatively lax regulatory framework. **Manufacturers of cough syrup were soon lacing their products with Bayer heroin.**

A 1901 ad for Heroin™ appearing in the American Journal of Pharmacy promoted the product to drug manufacturers as a cough medicine ingredient at the quite reasonable price of \$4.85 per ounce. Many of these cough products were subsequently sold over-the-counter.

BAYER Pharmaceutical Products

HEROIN—HYDROCHLORIDE

is pre-eminently adapted for the manufacture of cough elixirs, cough balsams, cough drops, cough lozenges, and cough medicines of any kind. Price in 1 oz. packages, \$4.85 per ounce; less in larger quantities. The efficient dose being very small (1-48 to 1-24 gr.), it is

The Cheapest Specific for the Relief of Coughs

(In bronchitis, phthisis, whooping cough, etc., etc.)

WRITE FOR LITERATURE TO

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In 1913, the large number of heroin-related admissions into U.S. hospitals in major cities presumably contributed to Bayer's decision to stop making the drug.

A burgeoning population of recreational users had emerged, some of them supporting their drug habit through the sale of scrap metal, thus earning the nickname "junkie."

Is the rest of the world *wrong*, but the U.S. *right* about hydrocodone use?

According to the UN-associated International Narcotics Control Board's 2011 report, *Narcotic Drugs*:

99 % of the Rx hydrocodone in the world is manufactured *and* used in the U.S.

The U.S. leads the world in the consumption of defined daily doses (DDD) of all Rx narcotics/ million people/day, with 47,800 such doses per day. A not very close second is our neighbor Canada, with 26,400 DDD/day (all DDD are per million people per day, thus population-adjusted).

The role of hydrocodone in total Rx narcotic use around the world

- Of the 47,800 DDD for all narcotics in the US, 26,500, 55% are for hydrocodone
- In Canada, only 258 DDD for hydrocodone out of 26,400 DDD for all narcotics, less than 1%
- In # 3 narcotics-consuming Germany, 34 hydro DDD out of 21,500 for all narcotics, < 0.2%
- Of the top 100 narcotic-consuming countries, only 1 (Canada) has more than 1% of the US DDD for hydrocodone. **Only 16 of the top 100 countries list any hydrocodone use. (None in 84)**

Figure 8. Federal False Claims Act (FCA): Financial Penalties by Industry, Fiscal Year (FY) 1991 – 2012

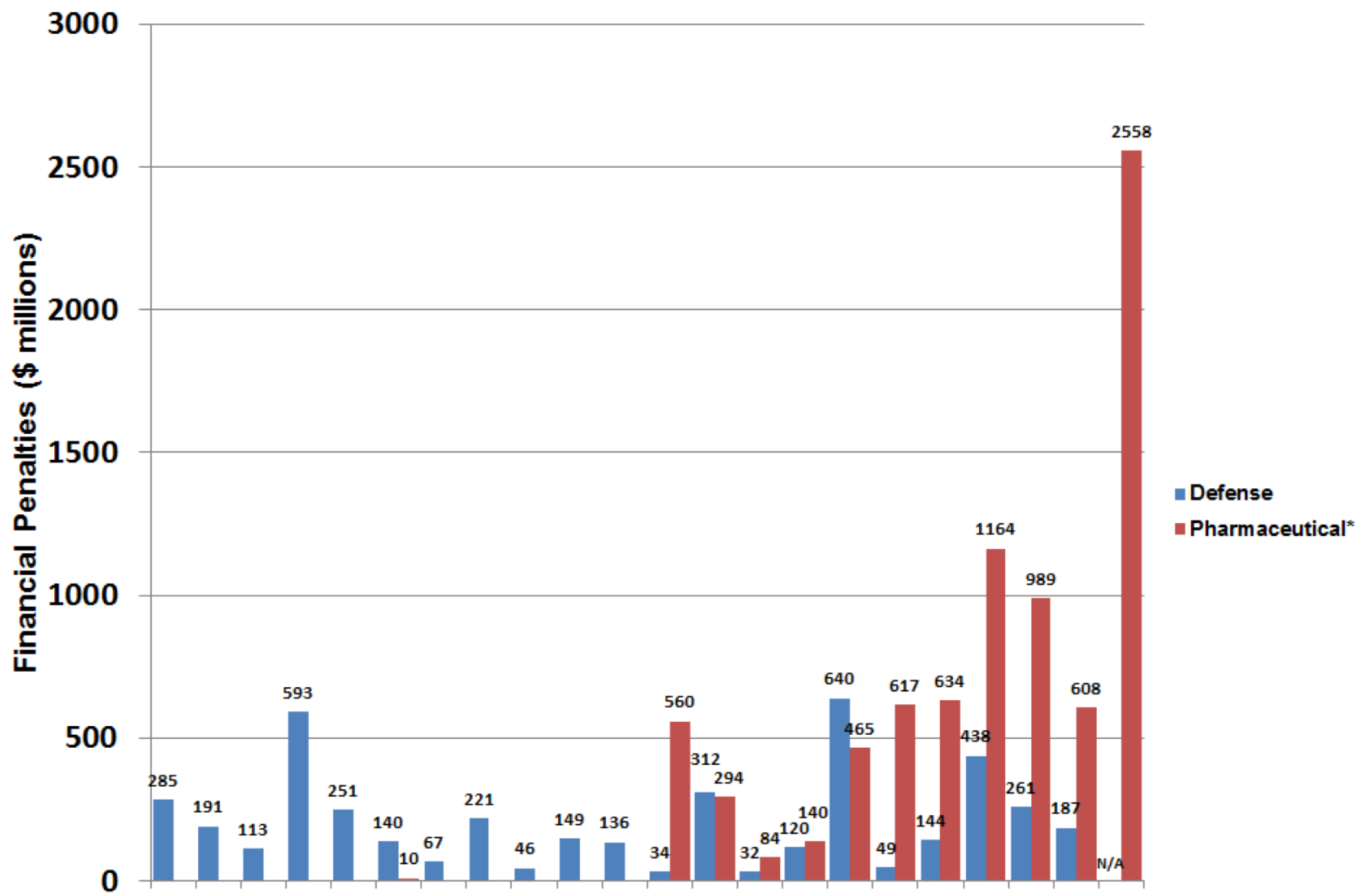


Figure D. Pharmaceutical Industry Financial Penalties: Civil vs. Criminal

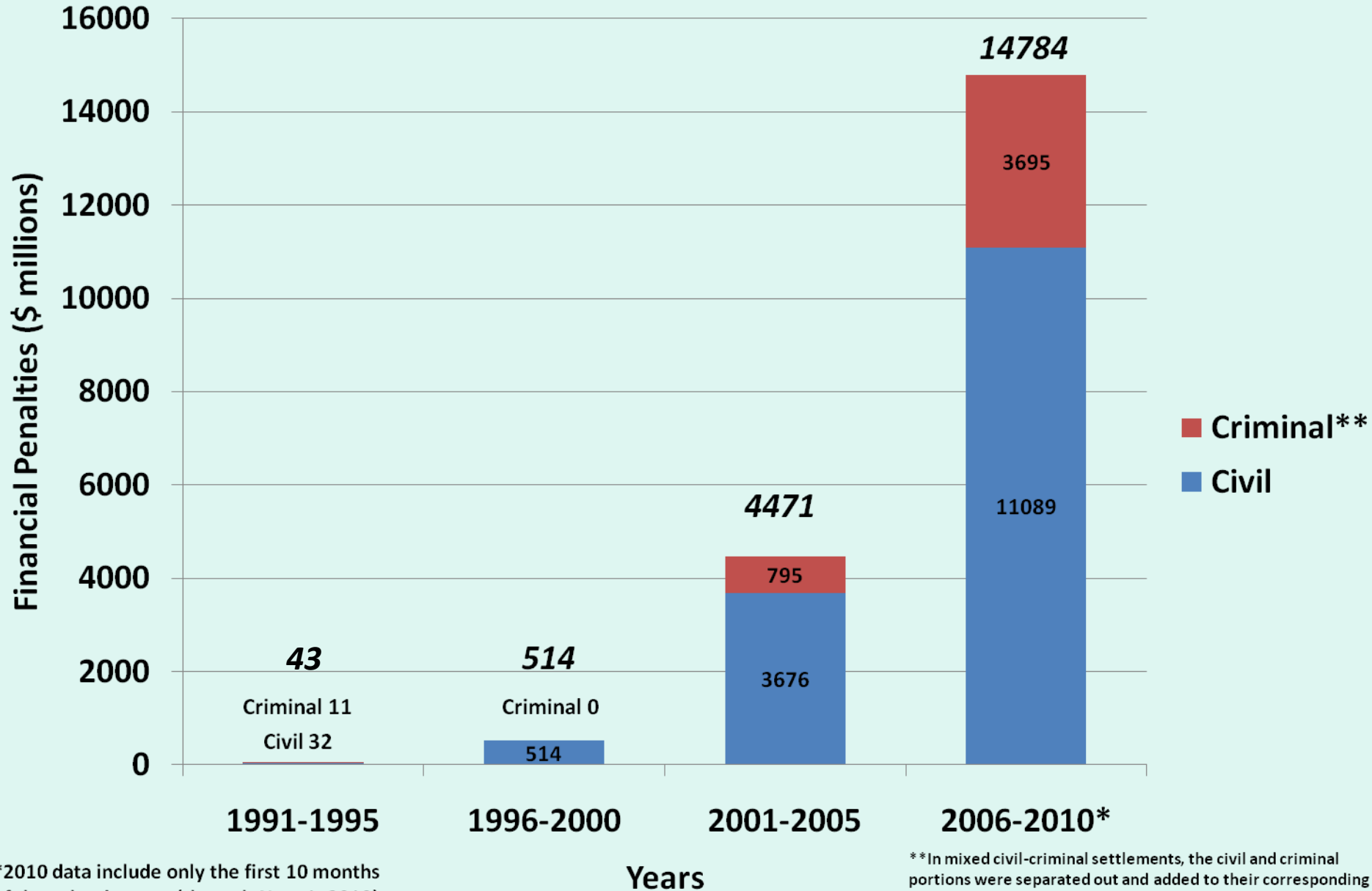


Table 5. Pharmaceutical Company Penalties: Worst Offenders, 1991 – July 18, 2012

Company*	Total Financial Penalties	Percent of Total†	Number of Settlements‡
GlaxoSmithKline	\$7.56 billion	25.1%	20
Pfizer	\$2.96 billion	9.8%	15
Johnson & Johnson	\$2.33 billion	7.7%	14
Merck***	\$1.86 billion	6.2%	27
Abbott	\$1.82 billion	6.0%	12
Eli Lilly	\$1.71 billion	5.7%	13
Schering-Plough	\$1.34 billion	4.4%	7

Methods for Research-Based Advocacy/Change

Research: Collect, analyze data, estimate risk, formulate petition to government agency, write report

Litigation: Against government if petition is not acted upon

Education, information: teaching, newsletters, books, medical journal articles, print and electronic media

Adverse Drug Reactions For Marketed Drugs in U.S.

- 2,000,000 serious ADRs yearly
- 100,000 annual number of ADR-related deaths
- 4th -6th: ranking of serious ADRs as causes of death

\$ 136,000,000,000 : annual cost

38 Public Citizen Petitions to FDA to Ban Prescription Drugs: 1971-2012

- 25 drugs (66 %) now banned
- 8 drugs (22 %) in very limited use
- 5 drugs (13 %) still in wide use

Drug Therapeutic Categories of Petitions

NSAIDS/analgesics	8	Darvon, Bextra, Suprol, Celebrex, Oraflex, Tandearil, butazolidin, Feldene,
Diabetes drugs	4	Phenformin, Rezulin, Victoza, Avandia
Antibiotics	3	Trovan, Ilosone, Tequin
Vasodilators	3	Vasodilan, Arlidin, Cyclospasmol
Others:		Meridia & Orlistat (diet), Serzone (antidepr), Cylert (ADHD), Trovan & Tequin (antibiotics), Aricept 23 (Alzheimer's), quinine (leg cramps), Hydergine (dementia), Halcion (sedative)

Generic Name (Brand Name)	Date Withdrawn in US	<i>Worst Pills, Best Pills</i> Readers Warned DO NOT USE
Rofecoxib (VIOXX)	September 2004	April 2001
Nefazadone (SERZONE)*	May 2004	February 2002
Cerivastatin (BAYCOL)	August 2001	March 1998
Alosetron (LOTRONEX)**	November 2000	August 2000
Cisapride (PROPULSID)	March 2000	August 1998
Troglitazone (REZULIN)	March 2000	January 1998
Grepafloxacin (RAXAR)	October 1999	April 1998
Bromfenac (DURACT)	June 1998	December 1997
Dexfenfluramine (REDUX)	September 1997	July 1996
Sibutramine (MERIDIA)	October 2010	March 1998
Propoxyphene (DARVON)	November 2010	May 1988

FDA
APPROVED
DRUG

WARNING:
CONTAINS
FDA
APPROVED
DRUG

Modelling for Victoza (liraglutide) for \$1000 for a half day of work (a version of “selling sickness”)

Would you like to earn \$1,000 for a half day of posing for ads promoting a widely-prescribed diabetes pill, Victoza — generic name liraglutide? A talent search agency in South Carolina recently announced a casting call for such people.

However, they most probably did not tell the potential models the following, from the drug’s label:

“Serious side effects may happen in people who take Victoza® , including:

1. Possible thyroid tumors, including cancer. ... It is not known if Victoza® will cause thyroid tumors or a type of thyroid cancer called medullary thyroid cancer in people. ...If medullary thyroid cancer occurs, it may lead to death if not detected and treated early.

2. Inflammation of the pancreas (pancreatitis), which may be severe and lead to death.”

If potential models were informed about this, those with ethical concerns might opt out of a campaign that will lead to more risks than benefits for people subsequently prescribed Victoza----despite the temptation of \$1,000 for a half a day’s posing.

Solutions

- **Research:** International research based on increasing amounts of internet-available government / industry data (EMA soon)
- **Regulation:** Why don't other countries' governments also face consumer/patient petitions? Open advisory committee meetings
- **Information:** Newsletters, books, medical journal articles, print and electronic media

Not prescribing or imbibing any new drug, except true breakthrough drugs, for the first 7 years after approval

The seven-year rule for safer prescribing

“A number of new drugs have been withdrawn within their first seven years after release. Also, warnings about serious new adverse reactions have been added to the labelling of a number of drugs, or new drug interactions have been detected, usually within the first seven years after a drug’s release.”

Aust Prescr 2012;35:138–9 S.M. Wolfe

Applying “Less is More” *

“Don’t do imaging for low back pain within the first 6 weeks unless red flags are present.”

“harms associated with early imaging for low back pain: including patient “labeling,” unneeded follow-up tests, irradiation exposure unnecessary surgery, and significant cost.”

“Routine imaging should not be pursued in acute low back pain.”

* Ongoing series in *Archives of Internal Medicine*, now *JAMA Internal Medicine*

“A Proposal for an Overtreatment Glycemic Measure”

- “Pogach and Aron suggest a performance measure that would penalize physicians and health care systems for a glycohemoglobin concentration of less than 7% among persons with diabetes who are older than 65 years and at risk for hypoglycemia. This measure of overtreatment and other similar measures have great potential to limit the adverse effects of overtreatment and to improve health.” **S.W.: Not rewarding overtreatment**

Recent JAMA Internal Medicine Articles

- “Undertreatment improves but overtreatment does not”
- “Less transfusion is likely more in acute MI”
- “Diagnostic Tests: Another frontier for less is more---or why talking to your patient is a safe and effective method of reassurance”

JAMA Archives editor Dr. Rita Redberg

- “A reminder to focus on addressing the issue the patient came into your office about is a good start. And, of course, a discussion of the chances of benefit and the chances of harm associated with additional tests or therapies helps patients (and us) to make informed decisions and to decline low value care.”

Health Research Group Petitions for Safer OSHA Health Standards

- Number of petitions filed: 19
- Number of petitions granted: 13 (68%)
(all granted only after litigation against OSHA)
- Petitions: worker hazard notification, benzene, ethylene oxide, cadmium, workplace smoking, chromium VI, resident work hours, beryllium

**Selling Sickness to Workers
as a trade-off for a job**

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