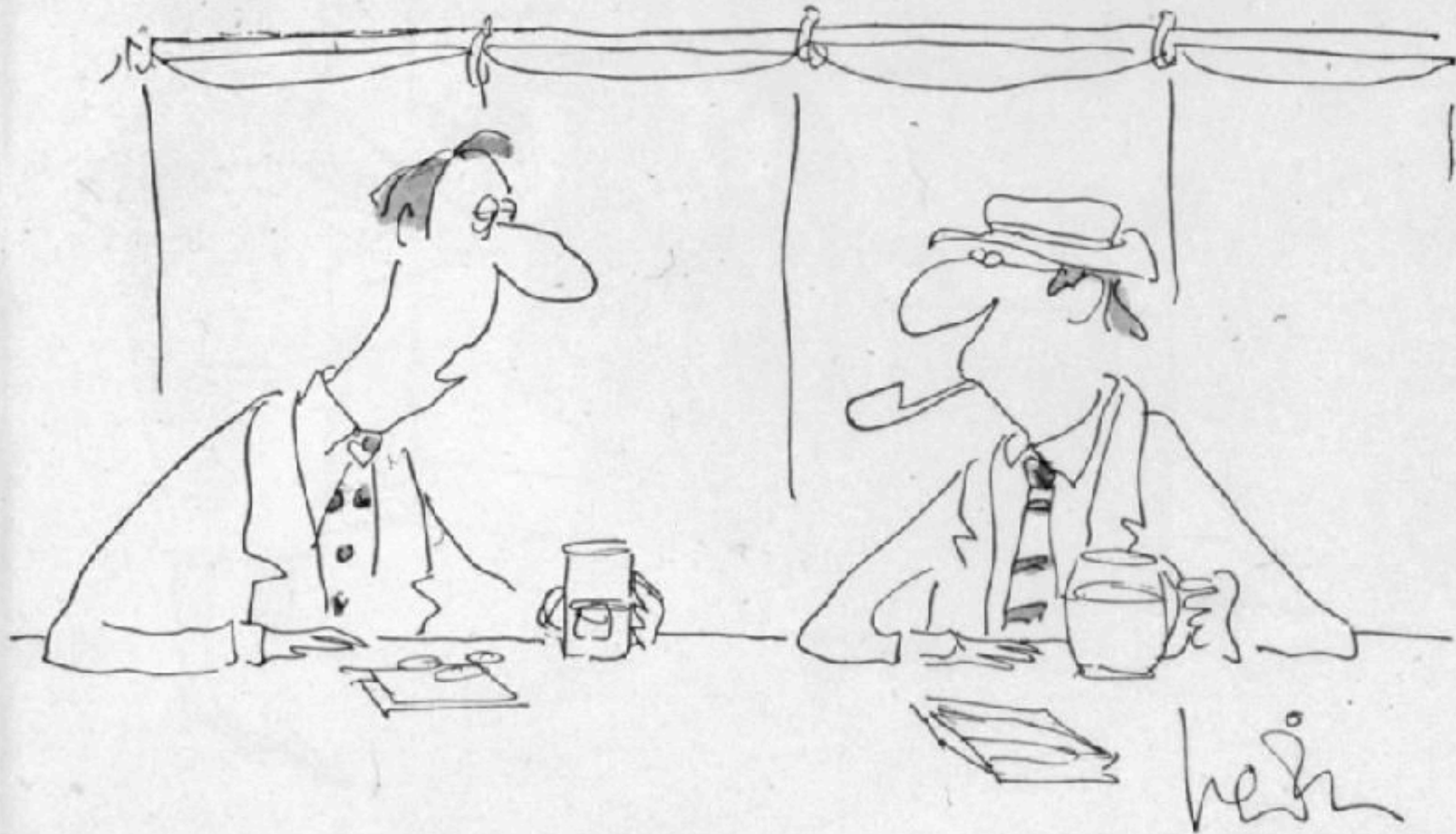


- **“Doctors pour drugs of which they know little, to cure diseases of which they know less, into patients of whom they know nothing.”**

- Moliere



"Well, I'll be damned if I'll defend to the death your right to say something that's statistically incorrect."

Conflict of Interest Disclosure

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- Consultant to: Abbott Laboratories, Aetna, Alza Corporation, Astellas Pharma Europe BV, Astra-Merck, AstraZeneca LP, Aventis Pharmaceuticals, Bayer Corporation, Berlex Laboratories, Blue Cross and Blue Shield, Biogen Idec, Bracco Diagnostics, Inc., Bristol-Myers Squibb Company, Centocor, Inc., Cephalon, Inc., Churchill Communications, Ciba-Geigy, Inc., Connaught Laboratories, CV Therapeutics, Cygnus Corporation, Inc., Daiichi Pharmaceuticals UK, Ltd., Dupont-Merck, Eli Lilly and Company, Ethicon, Forest Research Institute, GlaxoSmithKline, Hoechst-Roussel Pharmaceuticals, Inc., Hoffman LaRoche, IBEX Technologies Corporation, IMS Health, Inflexion, Inc., Inveresk Research North Carolina, Inc., IOM/National Academies of Science, Janssen Pharmaceuticals, Javelin Pharmaceuticals, Luitpold Pharmaceuticals, McNeil Consumer Products Company, Mediwound, Mikalix and Company, Novartis, Omnicare, Inc., Orchid Bioscience, Inc., Oscient Pharmaceutical Corp., Pfizer, Inc., PharMark Corporation, Quintiles Strategic Research and Safety/The Lewin Group, Inc., Rhone Poulenc Rorer Pharmaceuticals, Inc., Roche Laboratories, Inc., RW Johnson Pharmaceutical Research Institute, Sanofi-Aventis, Sanofi Pasteur, Inc., Schering-Plough Research Institute, Science, Toxicology, and Technology Consultants, Searle, Shire Pharmaceuticals, Syntex, USA, Inc., Takeda Pharmaceuticals North America, TAP Pharmaceuticals, Teva Neuroscience, Inc., Value Health Sciences, Warner Lambert, Wyeth Consumer Healthcare Division, and numerous law firms

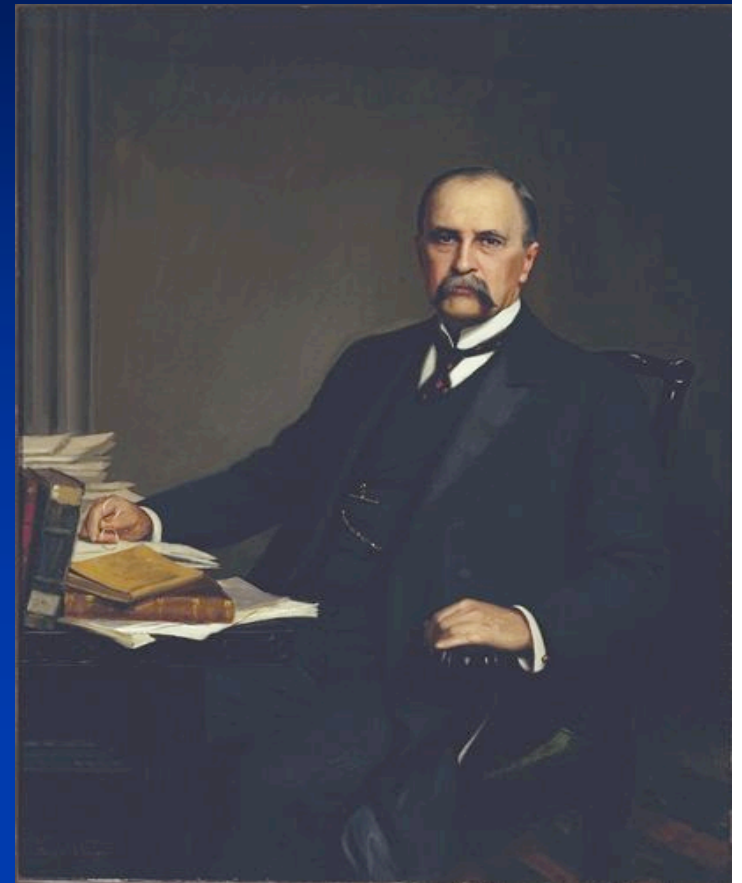


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Former Member of the Board of Directors of Medco Health Solutions, Inc.

Improving Drug Safety

- **“A desire to take medications is, perhaps, the greatest feature which distinguishes man from other animals.”**



Sir William Osler, 1891



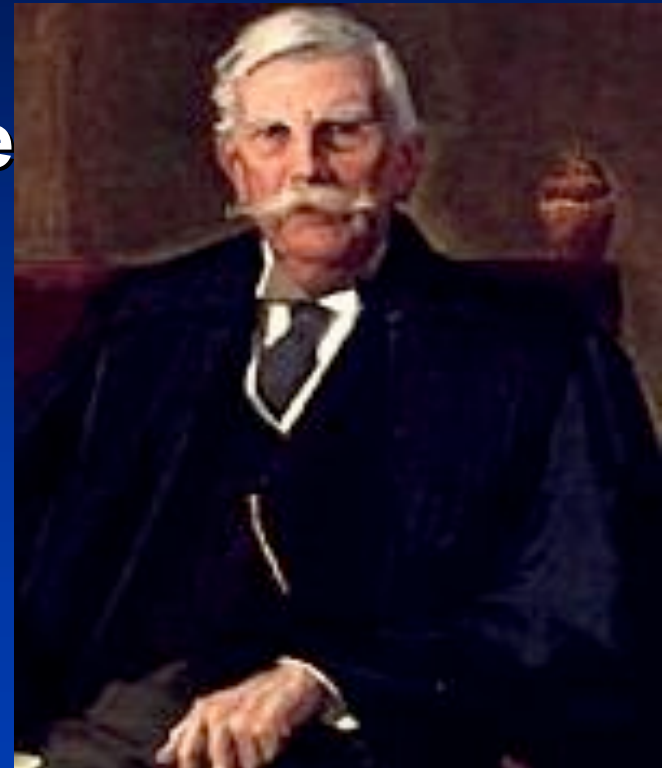
Improving Drug Safety

“If the whole materia medica, as now used, could be sunk to the bottom of the sea, it would be all the better for mankind, and all the worse for the fishes.”

Oliver Wendell Holmes

Medical Essays, “Comments and Counter”

Currents in Medical Science



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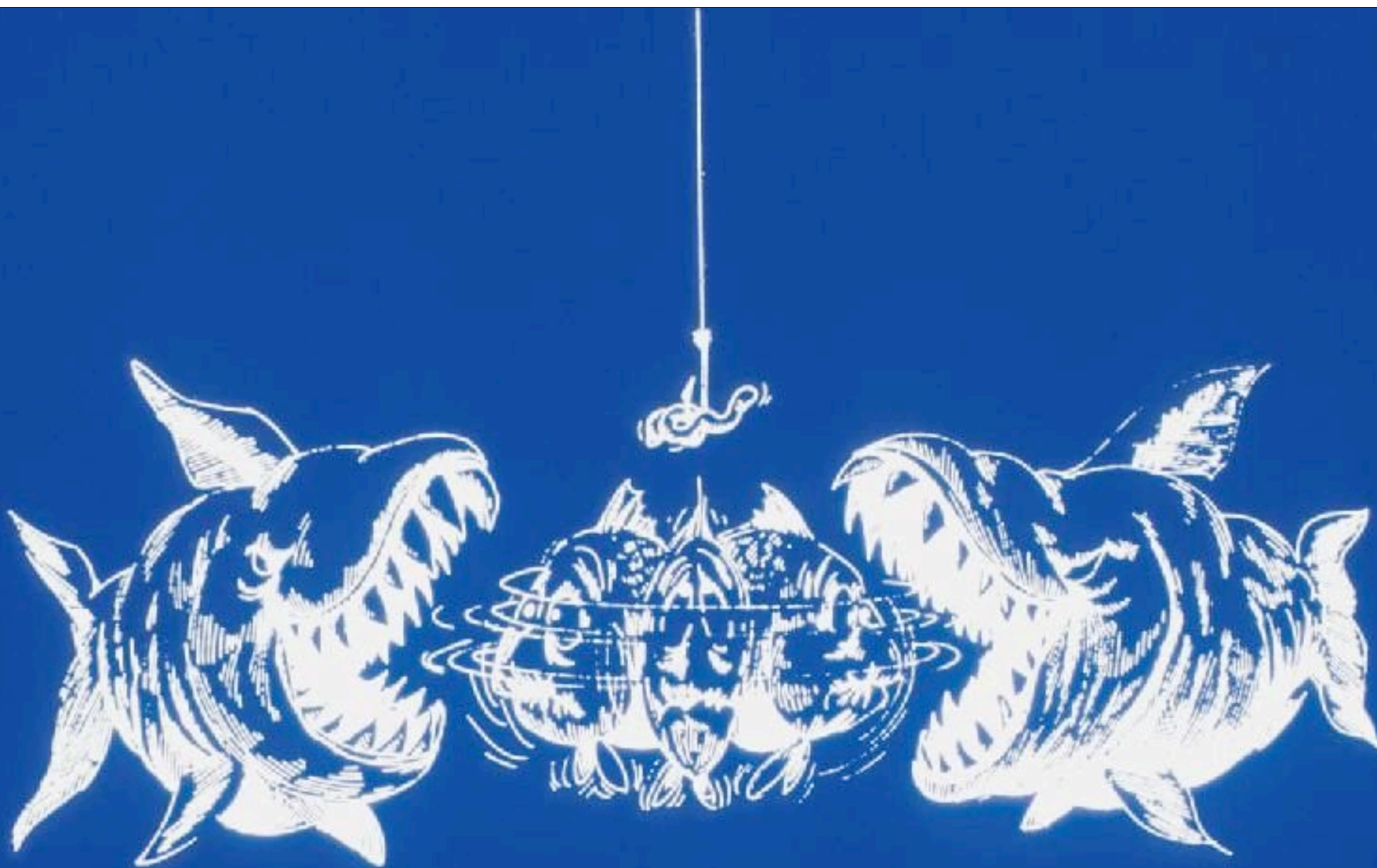
Today's Random Medical News

from the New England
Journal of
Panic-Inducing
Gobbledygook

JIM BERGMAN



Vandenbroucke, JP. Lancet 2004; 363:1729.



“Decisions usually involve risk.”

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ONE
GALLON

ELIXIR

ONE
GALLON

SULFANILAMIDE

Each fluidounce represents:

Sulfanilamide, 40 grs.

SUGGESTED FOR THE TREATMENT OF ALL CONDITIONS
IN WHICH THE HEMOLYTIC STREPTOCOCCI APPEAR

Dose, begin with 2 to 3 teaspoonfuls in water
every four hours. Decrease in twenty-four
to forty-eight hours to 1 or 2 teaspoonfuls
and continue at this dose until recovery.



THE S. E. MASSENGILL COMPANY
Manufacturing Pharmacists
BRISTOL, TENN.-VA.





Case Reports & Case Series

Cerivastatin (Baycol), an effective and inexpensive lipid lowering drug, was introduced in 1997. It was removed from the market in 2001 because of reports of fatal cases muscle breakdown (rhabdomyolysis).



MAYBE
WE SHOULD
GET A SECOND
OPINION.

RX



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R_x

...OF COURSE, WITH ANY
PRESCRIPTION DRUG,
THERE ARE SIDE EFFECTS...



PHARMACY

SALE



DRUG
CO.S



"Are you just pissing and moaning, or can you verify what you're saying with data?"

Definition: Epidemiology

- **Epidemiology is the study of the distribution and determinants of health and disease in populations, and is the basic science underlying much of public health and preventive medicine.**



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New Recommendations on Using Antibiotics Before Dental Procedures to Prevent Infection of Heart Valves

- **Introduction**
- **Background: Infective Endocarditis**
- **Study Design**
- **Results**
- **Conclusions**
- **Policy Results**



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Infective Endocarditis

- **An intravascular infection involving the heart valve(s) or endocardium. The diagnostic criteria are imprecise, and the diagnosis can be missed.**
- **High case fatality rate**
- **Great morbidity, high cost of treatment**



Host Risk Factors for Endocarditis

- In the past, 80-90% of cases on rheumatic valves
- More recently, 20-40% of cases on rheumatic valves and 15% on congenital defects, 2-12% on prosthetic valves
- ?Other valvular abnormalities, alcoholism, leukemia, meningitis, and immune deficiency diseases



Procedure Risk Factors for Endocarditis

- Procedures which provide opportunities for bacteremia, including possibly: IV lines, surgical procedures, urethral manipulation, abortions, infections, burns, insect bites, even rectal examinations and bowel movements



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Endocarditis Prophylaxis

- In order to prevent this serious disease, prophylactic antibiotics have been recommended before surgical and dental procedures
- Data underlying these recommendations are extremely limited, based mainly on animal models and in vitro data



All cats have four legs.
I have four legs.
Therefore, I am a cat.



Procedure Risk Factors for Endocarditis

- 4-14% of patients with endocarditis have antecedent dental procedures - is this high or low?



Objectives

To determine the risk factors associated with the development of infective endocarditis

- Host factors (especially mitral valve prolapse)**
- Procedures (especially dental treatment)**



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Conclusions

- **Infective endocarditis is an uncommon condition, although more common than previously thought, in large part because of intravenous drug abuse**
- **Prosthetic valves are major risk factors**
- **Congenital and other valve abnormalities are also important risk factors**
- **Mitral valve prolapse (irrespective of regurgitation) is a risk factor at least equivalent in magnitude to congenital and other valve abnormalities**



Conclusions

- A small minority of cases have pre-existing cardiac valvular disease plus recent dental work
- Thus, even if antibiotics were 100% effective, only a very small proportion of cases of this uncommon condition could be prevented by the current policy of widespread use of prophylactic antibiotics for dental procedures. A maximum of 1.3 cases/100,000/year would be prevented.



Conclusions

- **23.1% of cases had recent dental work (last 90 days)**
- **But so did 23.4% of controls**
- **Antecedent dental work does not seem to be a risk factor for endocarditis**



Conclusions

- **The current widespread practice of administering prophylactic antibiotics to those with cardiac abnormalities undergoing dental treatment should be reconsidered**



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W.D. Hamilton

“And it was so typically brilliant of you to have invited an epidemiologist.”