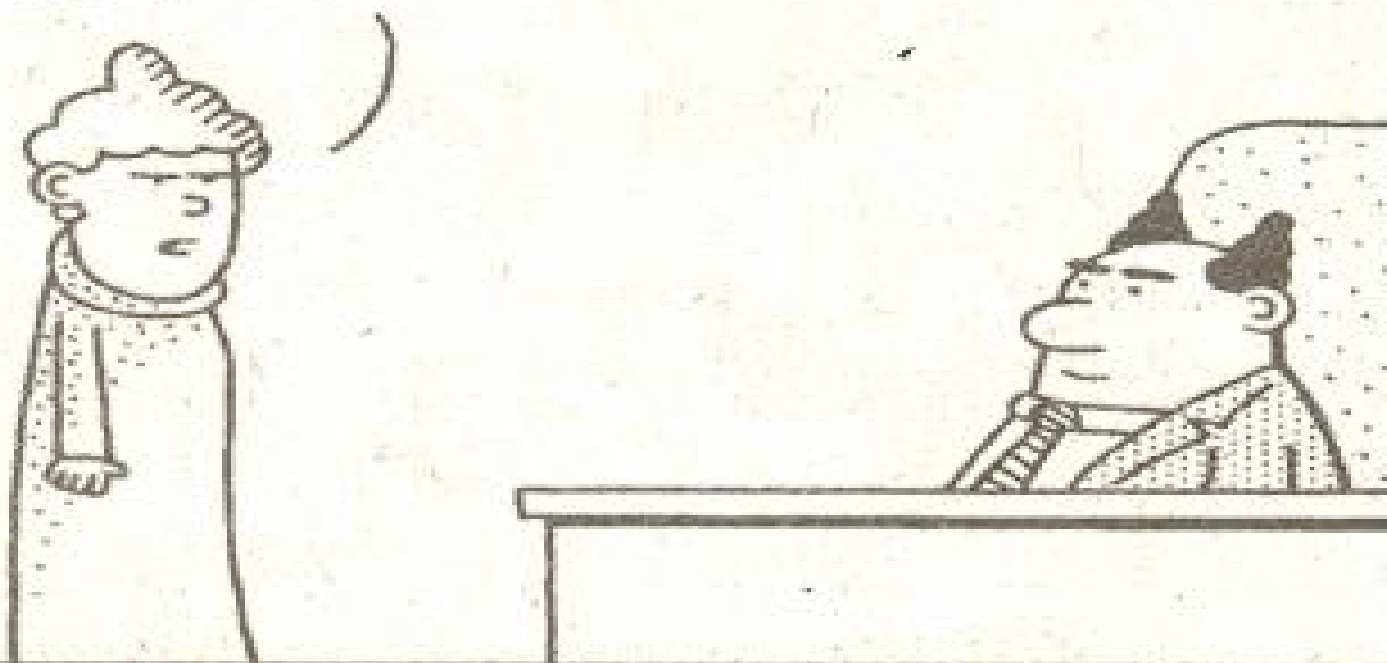


All you need is ignorance and confidence.
All else is assured.

Mark Twain

Dilbert

WOULD YOU CONSIDER
SPEAKING AT MY SON'S
SCHOOL ON "CAREER
DAY"?



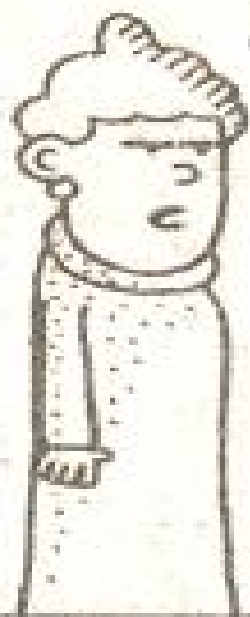
I'D DO IT MYSELF BUT
I CAN'T DISGUISE THE
BITTERNESS AND
DESPAIR THAT GNAW
AT MY SOUL.



By Scott Adams

PLUS MY SON HAS BEEN
BAD AND I TOLD HIM
I'D PUNISH HIM.

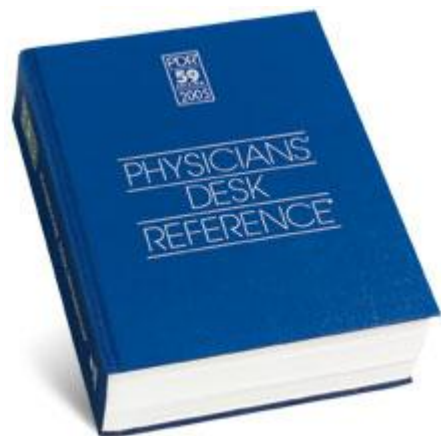
I'D BE
HONORED
TO SPEAK.





Conventional medicine:

Medicine as practiced by holders of M.D. (medical doctor) or D.O. (doctor of osteopathy) degrees and by their allied health professionals, such as physical therapists, psychologists, and registered nurses. Other terms for conventional medicine include allopathy and allopathic medicine; Western medicine, mainstream medicine, orthodox medicine, and regular medicine; and biomedicine.



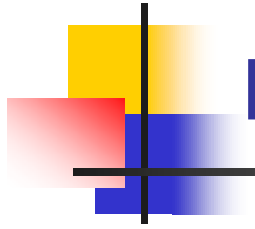
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PEDIATRIC USE

Safety and Efficacy of (Your drug name here) has not been established.

FACTS DO NOT CEASE TO EXIST BECAUSE
THEY ARE IGNORED.

Aldous Huxley

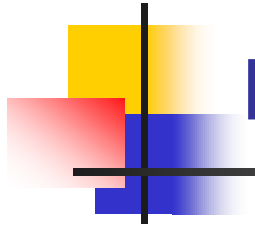


Barriers to Pediatric Drug Development

Ethical Constructs

Technology

Number of Age Groups



Barriers to Pediatric Drug Development

Regulatory Constraints

Financial Disincentives

- Small Populations

- Formulations

- Extended Liability

Lack of Political Will



Barriers to Pediatric Drug Development

Lack of Infrastructure

- Pediatric Pharmacologists
- Pediatric Clinical Research Units
- Pediatric Ambulatory Research Networks
- Pediatric Expertise on IRB's

Lack of Baseline Information

- Frequency of Disease
- Treatment of Choice
- Drugs of Choice of Disease States



Barriers to Pediatric Drug Development

- n Drugs that were not:
 - n Antibiotics
 - n Allergy/Cough/Cold Medication
 - n Asthma Medication
 - n Vaccines
- n Were not studied in pediatric patients



Benefits of Pediatric Drug Development

Huge Improvements in Chronic Diseases

- n Seizures
- n Asthma
- n Cystic Fibrosis
- n Leukemia
- n H. Influenza Meningitis/Epiglottitis



Benefits of Pediatric Drug Development

- n Seizures:

- n Two drug choices

- n One made you dumb

- n The other made you ugly



Benefits of Pediatric Drug Development

n Asthma:

- n 3 Shots of Epi followed by Suspherine®
- n Theophylline: Never sure if it would make you stop wheezing before it would make you seize.
- n The quality of life improvement with inhaled steroids and leukotriene inhibitors is hard to ignore



Benefits of Pediatric Drug Development

- n Cystic Fibrosis:

- n Why the longer survival time:

- n Increase emphasis on nutrition?
 - n The Vest?
 - n The inhaled antibiotics?
 - n Understanding enzyme replacement?



Benefits of Pediatric Drug Development

n Leukemia

- n The most obvious case for rational therapeutics.
- n Because virtually every pediatric patient with leukemia is enrolled in a clinical trial, the survival rate has skyrocketed



Benefits of Pediatric Drug Development

- n H. Influenza Meningitis/Epiglottitis
 - n Sometimes what is not there is the hardest to see.
 - n Effective vaccine introduced in 1988
 - n H. Influenza Meningitis/Epiglottitis are now mostly historical disease in the United States.



Benefits of Pediatric Drug Development

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Stopping by Woods on a Snowy Evening
by Robert Frost

Whose woods these are I think I know.
His house is in the village, though;
He will not see me stopping here
To watch his woods fill up with snow.

My little horse must think it queer
To stop without a farmhouse near
Between the woods and frozen lake
The darkest evening of the year.

He gives his harness bells a shake
To ask if there is some mistake.
The only other sound's the sweep
Of easy wind and downy flake.
The woods are lovely, dark and deep,
But I have promises to keep,
And miles to go before I sleep,
And miles to go before I sleep.

Thank you for your attention.

Questions???

