

## SCHROEDER LECTURE

### WORST PILLS, BEST PILLS<sup>†</sup>

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It is nice to be back here. I am also from Cleveland. Aside from my connections with the city, I still, intermittently, teach at the Case School of Medicine. I am an Adjunct Professor in the department of Internal Medicine.

Tonight, I am going to really focus on our book, *Worst Pills, Best Pills*, but more importantly, the principles in it that will, hopefully, be useful to some of you in terms of your own health, or the health of your children or parents, or whomever else. We originally published this book in 1988 because, having written articles and done a certain amount of work concerning prescription drug dangers, it seemed that there was a need for a book that really called the shots where they should be. So we titled the book *Worst Pills, Best Pills*. Originally, the book listed about a hundred or so drugs that were worst pills and for every one of the worst pills, we listed the safer alternatives. It is now greatly expanded. The book, I suppose, could be construed as an upper-body workout because it weighs four pounds or so. I gave a talk on the book, somewhat like tonight's, at the YMHA in Manhattan, last night. Barnes & Noble had set up this little place to sell the books—and several people went up and said, I would like to buy the book, but I do not want to carry it home. So, it was recommended that they go to their nearby Barnes & Noble store. So, it is, at once, a guide to dangerous drugs and also an upper-body workout, one arm at a time, or both arms.

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Why are we concerned about this problem? The following numbers are all from published studies and, if anything, they are probably significantly larger now than they were at the time. Two million serious adverse drug reactions occur, yearly, just in this country. A hundred-thousand deaths, adverse drug reaction deaths, and, I will repeat this over and over again, mostly preventable. And, depending what year it is, deaths from adverse reactions to drugs are between the fourth and the sixth leading cause of death in the United States, greatly exceeding automobile accidents, HIV, and other causes that people believe to be more common. Economically, it accounts for about \$136 billion a year—again, these figures are several years old so it is more than that by now. To the extent that it is preventable—preventable deaths, preventable hospitalizations, about a million-and-a-half people hospitalized every year because of an adverse drug reaction—something should be done about it.

The purpose of the book, in parallel with our efforts to get the FDA to ban or put stronger warnings on these drugs, is to try to encourage patients do something about it. In addition to the million-and-a-half people I mentioned who are hospitalized because of adverse drug reactions every year, another three-quarters of a million people, who were fine when they came into the hospital, developed, in the hospital, an adverse drug reaction. So the toll of adverse drug reactions is enormous in terms of adverse affects on the public health.

Concerning emergency room visits, a recent review of all the studies asked the question, how often does someone who goes to the emergency room go there because of an adverse drug reaction? This review found out that 28 percent of all emergency department visits were drug-related including a large portion due to adverse drug reactions and inappropriate prescriptions. Again, the point was 70 percent were preventable.

When we first put out our book, *Worst Pills, Best Pills*, it simulated some medical researchers to come up with lists of drugs that, really, should not be used, specifically for older adults. They came up with lists that were much shorter than ours because they wanted to be absolutely clear, although we think ours are more than clear enough. Some of these people have looked at national data and asked the question, how many people, nationally, are taking one of these inappropriate or potentially inappropriate drugs? In a fairly recent study 6.6 million people a year were taking a potentially inappropriate drug. Now, this is of a much smaller list than we have. It is, probably, twenty or thirty drugs instead of the now 181 that we list in our book as “Do Not Use.” So overall, of the 181 drugs that we list in our book as “Do Not Use” fifty-three or 29 percent are amongst the top selling two hundred drugs. This is based on retail prescriptions filled in 2004. These fifty-

three drugs cost \$22.2 billion in 2004. Again, for every drug that is a “Do Not Use” you can turn to another page in the book and find a drug which is safer and often, an older drug.

This is just a very small example of some of the “Do Not Use” drugs: sleeping pills like Valium, Restoril, Ativan, Tranxene; antidepressants such as Serzone, Elavil; painkillers, Vioxx would be on the list except it is off the market. We warned people to stop using Vioxx four-and-a-half years ago when it was clear, from a well-done study funded by Merck, that it was causing a four-fold increase risk in heart attacks. Darvon, Darvocet, basically worthless painkillers; addicting and cause cardiac toxicity. The toenail fungus drug, Lamisil, probably many of you have seen cartoons about little fungus things crawling around people’s toenails, making your toenails look ugly, which is a cosmetic problem. The drug causes severe and often fatal liver toxicity, rarely. But there are dozens, if not by now, hundreds of cases of liver toxicity and to trade-off a cosmetic advantage for your toenails for liver toxicity we do not think is a good idea, so it is listed as a “Do Not Use” drug.

Other “Do Not Use” drugs include Crestor, the newest of the cholesterol lowering drugs. Crestor is a drug we tried to keep off the market. We did not succeed, but since it has been on the market we have been attempting to get it taken off the market. I think it, eventually, will come off the market. Others in this category of heart drugs are Lopid, Catapres and more. “Do Not Use” gastrointestinal drugs include Donnatal, Librax. There are also several diabetes drugs and birth control pills. And just last week, another birth control device, a patch called OrthoEvra, has come under scrutiny. We actually warned people to stop using it a couple years ago. It gives a much higher dose of estrogen and causes a higher rate of blood clots than the older pills. Three other birth controls also contain an ingredient, not the estrogen, but the progesterone content of the pill, which causes increased blood clots, so we say do not use those.

The list of thirty “Do Not Use” drugs including the ones just mentioned, have 228 million prescriptions a year filled, a cost of over \$12 billion a year. In many of the most commonly prescribed categories of drugs we discuss in the book: mind drugs (tranquilizers, sleeping pills, antipsychotic drugs), heart drugs, gastrointestinal drugs, pain and arthritis drugs, large proportions of them, respectively 43 percent, 20 percent, 31 percent and 37 percent are on our “Do Not Use” list.

We published in the *Journal of the American Medical Association* about three years ago in which the question we were asking was: What happens, on the average, to a drug once it comes on the market? We looked at every new drug approved by the FDA between 1975 and 1999. There were 548 such drugs. We found that of the 548 new

drugs, fifty-six had either been taken off the market or were the subject of a black box warning.

We concluded that by the time drugs have been on the market for twenty-five years, one out of five drugs were either withdrawn or required a new black box warning. And most of this was in the first seven years after approval.

Our conclusion from this and from other work is to recommend that nobody use any new drug unless it is a breakthrough drug, of which there are some but not very many. Specifically, do not use any new drug until it has been on the market for seven years because that is the time where most of the surprises are going to happen. Unless you want to be part of the surprise, we urge you and physicians who take care of you to stay away from these drugs.

We now move into the area of a topic that we focused on heavily when we first did this book and continue to focus on heavily, and which is often confusing to the physician and patient: the issue of drug-induced disease. You get to be sixty or seventy and you start losing your memory or you start developing Parkinson's disease or you start having other problems: falling down, having hip fractures. The tendency is to say, "Well, too bad, you are getting old. That is just a part of growing old." However, the book includes well-documented examples of people who had, not just age related problems, but had adverse drug reactions. Some examples include: arrhythmia; causing the death of someone; Parkinsonism in someone who really started having Parkinsonism after a drug was prescribed and only after a wise neurologist discovered this were they taken off the drug causing it and the Parkinsonism vanished; memory loss.

The person who wrote the Preface to our book is Dr. Eric Larson, a physician at the University of Washington of Seattle who discovered and documented two clear instances of drug-induced disease. One was reversible memory loss. A large number of drugs can cause memory loss. If you are sixty or seventy and you start losing your memory it may look like early Alzheimer's. And, often, it is. But often, it is an adverse drug reaction problem and fortunately, those are all reversible. Dr. Larson also discovered the relationship between using certain drugs and having falls and hip fractures. There are numerous examples, case examples, well-documented, of drug-induced disease. So just focusing on this and, more broadly, this issue of one hundred thousand deaths and two million serious adverse drug reactions: what do we do about it?

Something should be done about drug-induced illnesses to the extent that they could be reversed entirely or largely by reducing the dose of the drug or switching to another drug. Something should also

be done to the extent that, too often, the average drug reaction, when it appears to be a new “disease”, is treated with another drug.

When we first did our book in 1988, a woman was referred to me who was about fifty and had documented low thyroid levels. She was, appropriately, put on a thyroid medicine to treat the low thyroid levels. However, she was put on too high a dose and, for some reason, was taking it very late in the day. As a result, she developed insomnia and was put on a sleeping pill. Because she was on a sleeping pill, she became depressed and was put on an antidepressant. Sleeping pills, not infrequently, can cause depression. Thus, she was put on an antidepressant to treat the depression that was caused by the sleeping pill, the need for which was caused by the way she was taking her thyroid medicine. We arranged, with her physician, to lower the dose of thyroid medicine and for her to take it early in the morning instead of late in the day. She stopped having insomnia and needing the sleeping pill. She therefore also stopped needing the antidepressant to treat the depression caused by the sleeping pill. This is an example of the sort of cascade of drug-induced diseases being treated with drugs instead of prevention. The book lists 166 drugs can cause depression. 156 drugs that can cause hallucinations or psychoses.

Sexual dysfunction is an interesting issue. A year after Viagra came on the market, I looked through the FDA’s files—legally with permission—at all of the cases of adverse reactions reported with Viagra. I was more interested in what other drugs these people were taking than in the actual nature of the adverse reactions. What I found was half of the people who had an adverse reaction to Viagra were taking one or more drugs that can cause sexual dysfunction. Whereas this was occurring in men who were also using Viagra, many of these same drugs, these SSRI’s (Selective serotonin reuptake inhibitors), Prozac, Zoloft and so forth, can also cause sexual dysfunction in women. Again, if the sexual dysfunction is drug induced, the treatment might more optimally be to change drugs or to lower the dose, as opposed to taking Viagra or Levitra or Cialis, to treat what is drug-induced sexual dysfunction.

There are other examples of drug-induced illnesses. As already mentioned, our friend, Dr. Eric Larson, discovered well-documented, reversible dementia in older people. Hip fractures from falling, another category. More examples of drug-induced problems include auto accidents, falling asleep, and insomnia. Thyroid medication, including Synthroid, and quite a few other drugs can also cause insomnia. Again, most of the people taking these drugs who have insomnia are given sleeping pills, even though there should be other ways of dealing with this. There is also the serious problem drug-induced Parkinsonism.

We categorize areas of problems where prescriptions are written where they should not or where it is the wrong prescription. We call these seven all too-often-deadly sins. This is not meant to be a religious treatise.

First, the disease for which the drug is prescribed is actually an adverse reaction to another drug—we have just given some examples—masquerading as a disease.

Second, the drug is used to treat a problem that, although is susceptible to a prescription drug or over-the-counter drug solution, should, first, be treated with commonsense lifestyle changes. A huge proportion of people with mild hypertension, with mild adult onset diabetes, with mild obesity or being overweight, should first be tried with lifestyle changes. Unfortunately, too many physicians are not adequately trained in nutrition or discussions about exercise and it is much easier to just write a prescription. This is particularly so when a drug salesperson is yelling in your ear that this is the way to take care of these problems.

Third, the medical problem is both, self-limited and completely unresponsive to treatments. An example is the use of antibiotics for viral infections when no antibiotic will work at all and an antibacterial, certainly, will not work. A lot of self-limited diseases, a cold being a good example, will get better in seven days with certain drugs and in a week without certain drugs. The net impact of the certain drugs is often really certain adverse reactions. An example is insomnia because some of these cold medicines have a decongestant which is an amphetamine-like upper. We have argued for twenty-five years no one should ever take a systemic decongestant because you are getting, roughly, twenty-five times more drug than if you squirted some spray in your nose and with all the dangers of inherent. PPA or phenylpropanolamine, which was an ingredient in a lot of cold preparations, was taken off the market after it was shown to cause hemorrhagic stroke. It is an upper and increases blood pressure and can cause strokes.

Fourth, a drug is the preferred treatment but instead of giving you a safer alternative, one of the 181 “Do Not Use” drugs is recommended. Obviously, it is not just self-serving for me to say: stay away from “Do Not Use” drugs. There are safer alternatives.

Fifth, drugs interact. Most people, including many physicians, have a misperception as to what a drug interaction means. It does not mean that if you put the two drugs together an explosion occurs. What it does usually mean is that one drug will stop the body from efficiently getting rid of the other drug. So, if you take two drugs that interact, the first one may inhibit the liver’s ability to get rid of the second drug, and therefore, you may accumulate dangerous levels of

the second drug, not because you were prescribed dangerous levels, but because the body could not effectively get rid of it.

Sixth, another problem is physicians who prescribe two drugs in the same therapeutic category—sometimes it is necessary, but more often it is not. Often, the second drug does not have any evidence of increasing the effectiveness of the first drug but it incurs an additional risk. Thus, there are two risks, but one benefit. This is not a good deal.

Seventh, the right drug is prescribed, but the dose is too high. This is particularly true in older adults. We will go through some reasons why older adults have more difficulty with prescription drugs and why in probably 98 percent of the cases they should always be started with a lower dose. An older adult includes me, and has included me for more than twenty years, because some of these changes in the liver and kidneys start at age forty or fifty.

Next are nine reasons why older adults should pay particular attention to the drugs they are prescribed. Older adults have smaller bodies and different body composition. When we get older our weight, generally, goes down. It may seem to go in the other direction for a while, but we have a smaller amount of water. To the extent that a lot of the drugs are water-soluble, the same amount of drug will dissolve in a smaller amount of water and therefore the concentration will be higher. There is also decreased ability of the liver to process drugs and for the kidney to get drugs out of the body. The decrease in kidney function starts at age thirty-five to forty and by the time we are sixty-five, the filtering ability has decreased by 30 percent. These are not people with kidney disease or liver disease, just people who are aging and these two organs that are so crucial to drug metabolism or elimination are not working as well as they used to. It gets, obviously, much worse if you also have kidney disease or liver disease.

In addition to decreased body size and less water and higher drug concentrations, even at normal blood levels, older people may be much more sensitive to drugs than younger people. How many of you who are over sixty, when you get out of bed in the morning, sit on the edge of your bed for at least ten seconds before standing? Why is this important? When we are younger and we get out of bed the blood tends to rush to the bottom of our body just by gravity, but, instantly, our more effective, younger homeostatic mechanisms constrict the blood vessels and it happens so quickly that the blood pressure is not allowed to fall. This does not work as well when we are older. So either when you are getting out of bed you should sit on the edge of the bed or when you are standing, after sitting, stand by the chair for five or ten seconds. This is a major cause of falls and it is largely avoidable. Compounding this though, are people who are also taking blood pressure medicines. In addition to not being able to compensate

for the gravitational effect, you are taking a drug which may lower your blood pressure. Although even if you are not taking high blood pressure drugs, it is important to do this healthy hesitation for a few seconds.

Decreased temperature compensation is another problem that increases when one is older and may be worsened if using certain prescription drugs. One of the first things I did when I arrived at NIH in 1966 was to study how much water you had to drink to avoid going into negative fluid balance when it was warm outside. It is amazing how much sweat you can produce when it is hot. Humans would die if they did not sweat, period. The only way we stay alive in a hot environment, other than air-conditioning, is to sweat. It evaporates and it cools the body. Normally, if it is very, very hot outside, we are able to divert almost all of our fluid to sweat and thereby help us stay in good health. Certain drugs interrupt this diversion of fluid into sweat and force a certain amount of fluid into the urine. For diuretics, for example, that is the way they work. When it gets very hot outside it is all the more important to pay attention to drugs you are taking that might cause fluid loss and to drink more liquids.

Diseases affect the body's response to drugs. I mentioned earlier that even if you do not have liver or kidney problems those functions decrease with age. But, if you do have these problems, they make it even more difficult to figure out the right dose of drugs and make it even more necessary to use lower doses. More drugs equal more adverse reactions. Obviously, if you take one drug you can have an adverse reaction. If you take two, the odds increase including the possibility of an interaction. Many older people, however, are taking six, seven, eight drugs. I am happy to report—she would not attack me for saying this—that my ninety-seven-year-old mother is taking one prescription drug and she is in very good health and has somehow survived without taking a lot of prescription drugs. The point is, once you start—and obviously, many people need to take more than one drug,—as you go up in number, you multiply the possibility for reactions and interactions. It is a geometric, not an arithmetic increase in possible interactions.

A favorite quote is about the fact that older people, who take the most drugs, are often the least used subjects for finding out about these drugs. Dr. Peter Lamay, who was at the University of Maryland School of Pharmacy, who died about fifteen years ago, said, “We test drugs in young people for three months; we give them to old people for fifteen years.” And for the reasons I have just pointed out, old people and young people are very different in many respects.

Our book also contains ten rules for safer drug use. The first rule, have a “brown bag session” with your primary doctor and fill

out a drug worksheet, you all have heard of but I am not sure how many of you have done it and do it completely. People are taking, not only prescription drugs, but also over-the-counter drugs, and an increasing number of people, unfortunately, are taking dietary supplements. One of the chapters we added to this book, which had not been in there in previous editions, was a review of thirteen of the biggest selling dietary supplements. We found that none of the thirteen dietary supplements would pass the test of being effective and safe if they had to. However, because of a law, which Congress passed, dietary supplements do not have to be shown to be safe or effective. And companies do not have to report deaths or any adverse reactions. But the people who take these on their own, as is the case for over-the-counter drugs, often are embarrassed to tell or do not tell their physicians. So, the first rule is to let your physician, and hopefully it is a primary care physician which is what rule ten is, know everything that you are using because the odds are that they may say, "Wait a minute, this interacts with this. You probably should not be using one of them." And the most dispensable one would be dispensed with.

Rule two is to make sure drug therapy is really needed. This is a corollary of what I said earlier that a lot of times, problems that are either self limited or problems that could benefit from non-pharmacological solutions are immediately treated with drugs.

Rule three, if drug therapy is indicated, in most cases, especially in older adults, start with a lower dose and go slowly up. This is much safer than starting with a higher dose and getting an unnecessary adverse reaction. Many people are taking five, six, seven drugs and the most dispensable of those should be the one that maybe is stopped if it is really necessary to take another drug that really is critical.

Rule five is that stopping a drug is as important as starting it. For reasons we do not fully understand, in many who have been taking an anti-hypertension drug for several years, their need decreases. Periodically attempt, with a physician, to lower the dose of an anti-hypertensive drug and you will many times see that the blood pressure stays the same and when you lower it down to nothing, it may still stay the same. Not something you should do on your own but a way of, again, reducing exposure to drugs.

Rule six is to find out if you are having any adverse drug reactions. Studies thirty-five years ago, and recently, show that many physicians, a majority, do not adequately inform people about known risks of prescription drugs. Thus, when the person takes the drug and develops what is, in fact, an adverse drug reaction, they think, well, maybe this is just a turn for the worse in my disease and they do not make the connection and therefore, do not call the physician and

therefore, have a longer period of adverse drug reactions than they should.

Rule seven is probably as important as any, which is once you start taking a new drug and you develop a new symptom, the default should be: this is an adverse drug reaction until proven otherwise. If you have books or information that point this out fine, but in any event tell your physician about it because this may be the beginning of what is a serious adverse reaction and you and your physician should possibly lower the dose or switch away from that drug. This is particularly true for older people but even some younger people.

Rule number eight is that before leaving the doctor's office make sure that you know how to take the medicine and the issue of adverse reactions are clear to you and a family member or friend.

Rule number nine is: discard all drugs carefully. There was actually, not funny but it was, at some level, an amusing article on the front page of the *New York Times* this morning, long after we proposed this rule, which is seventeen years old. The article in the *Times* was about a whole circle of trading drugs among friends. This is dangerous because someone may not have the disease that the amateur physician thinks that they have and they might have a very bad reaction to the drug. Someone may be taking another drug unbeknownst to the drug-hander-outer. So, discard all old drugs carefully is a good rule.

Finally, as I mentioned before, rule number ten is that everyone needs to have a primary-care doctor. This is not self-serving because I am a primary-care general internist, but because too often, older people wind up going to the kidney doctor, the heart doctor, the gastrointestinal doctor and the neurologist and no one is coordinating the care leading people to get prescriptions for drugs that if one doctor knew about what the others are prescribing the drug would never all be prescribed.

Another section of the book advises how people can save money when buying prescriptions. Five rules include asking, if appropriate, for non-drug treatment. These rules are, obviously, overlapping with some of the lists of suggestions discussed above. Avoid "Do Not Use" drugs. Over the years, many of the drugs that we said "Do Not Use" have been taken off the market. As I mentioned before, because of the study we did and because of other evidence, do not use new drugs unless they are a breakthrough drug for at least seven years. By then, by definition, they will be safer if they are still on the market and, at least, you will know through a black box warning about some of the newly discovered problems.

Buy generic drugs. There is no evidence, whatsoever, that generic drugs are any less effective or safe than brand name drugs. More and

more expensive brand name drugs are coming off patent. You should use generic drugs. Finally, we think that purchasing drugs from Canada and importing them or using Internet purchase can be very good but you have to be very careful. There are a lot of charlatans in this country who have web sites where you do not need to have a doctor and there is only a computer version of a pharmacist that actually does the prescribing and dispensing and, unfortunately, the medical boards and the pharmacy boards have not disciplined the physicians and pharmacists who are lending their names to these web sites as much as they should.

In thirty-four years, we've asked the FDA to ban twenty-seven prescription drugs. Two-thirds of them, or eighteen, are off the market now. Another four, the use is severely limited and five of them, or nearly 20 percent, are still on the market. These are, mainly, recently approved drugs like Celebrex and Crestor. We tried to get the FDA to ban Celebrex at the same time we tried to get them to ban Bextra. Although they have left Celebrex on the market, this is a mistake because it has increased cardiovascular risks as well.

This year, through an act of Congress that was passed thirteen years ago called the Prescription Drug User Fee Act, the FDA gets more than \$200 million in cash directly from the drug industry to fund a good proportion of its drug review functions. Those who say it does not have any influence on the FDA to get funded from the industry that it is supposed to be regulating it are wrong. There are lots of people, physicians and others in the FDA, who are starting to think that their client is not the public entirely, which is what should be, but it is also the industry. The lax FDA behavior since this law was passed, accompanied by sharply decreased congressional oversight, has led the FDA to be far less vigilant than it used to be in the 70s and 80s, when I first started doing this work.

Finally, a little bit on advertising. The *Garden of Folly* is a wonderful, short book written by a Canadian economist, Stephen Leacock, eighty-one years ago. The "folly" is advertising and it includes the most poignant definition of advertising I have ever seen. "The science of arresting the human intelligence long enough to get money from it." This idea is not just relevant to direct-to-consumer advertising to patients, but also to advertising and promotion of drugs to physicians with as much misleading information as the companies can get away with.

We have been tracking, for more than a decade, the FDA's enforcement activities over prescription drug advertising. Either in the form of warning letters or other letters, the FDA enforces the law and regulations concerning prescription drug advertising by notifying drug companies that they must stop certain ads because they are illegal. The

legal bases for which these ads are deemed illegal include overstating the benefits, understating the risks and not having an adequate balance between benefits and risks. 1998, at the peak of FDA's activity in this area, they stopped 157 illegal prescription drug ads. The amount of drug ads has rocketed since then. So, if the ads were no better, no worse than they were in 1998, one would expect a big increase in the number of enforcement actions. Instead, during the Clinton administration, the number of enforcement actions started rocketing down, significantly, to the point where last year, 2004, it was down to twenty-four, an 85 percent decrease in the amount of activity that the FDA is exerting through the law and regulations that they are supposed to be upholding. And the message to the industry is that they can just mislead people. Of course, a misleading ad may result in a dead patient because if a physician prescribes a drug based on thinking the drug is safer and/or more effective than it really is, the doctor may write a prescription for something they would not have written for if they had been adequately informed. So, advertising enforcement is very, very important.

In his introduction to *Worst Pills, Best Pills*, Dr. Eric Larson has said that although we are, appropriately, harsh with those drugs that we designate as DO NOT USE, we are not inappropriately harsh so that patients should be hopeless or cynical. One should use the information to tell the difference between the best pills—the safer, equally or more effective pills—and the ones you should stay away from, the worst pills.

Over the years, we have warned patients to stop using certain dangerous drugs as long as several years before they were banned. Vioxx is such an example, wherein we told people to stop using the drug in early 2001, more than three years before it was pulled off the market. Another is the cholesterol-lowering drug, Baycol. When we make these “do not use” recommendations, we base our conclusions on data, often unpublished data, that we got from the FDA, sometimes having to sue them to force some of these company studies to be released. So, over and over again, we have predicted, usefully—for those people that get this information—the dangers of a drug before we have, through the regulatory part of our work, gotten the FDA to ban them.

All of the contents of our book *Worst Pills, Best Pills*, our monthly newsletter *Worst Pills, Best Pills News*, and drug safety alerts are now on our web site [Worstpills.org](http://Worstpills.org).