Editorial: Bernard Rimland, Ph.D.

The FDA's risk/benefit strategy: your risk, drug companies' benefit

One of Dr. Rimland's greatest concerns was mainstream medicine's focus on using dangerous drugs to mask symptoms of autism, rather than treating autistic children's underlying problems. He wrote this editorial shortly before he passed away.

Need a definition for the phrase "double standard?" Just look in the dictionary under "Food and Drug Administration."

In October of 2006, the FDA approved the use of Risperdal (risperidone) to treat aggression and other symptoms in autistic children. A spokesman for the FDA announced that the approval—based on two eight-week trials—"should benefit many autistic children as well as their parents and other caregivers."

How did the FDA come to that conclusion? By ignoring the scientific evidence of risperidone's terrible side effects -- and by refusing to acknowledge that non-drug treatments are equally effective and *pose virtually no risk*. For the FDA, it's par for the course.

Miracle pill or deadly drug?

Risperidone is the first drug approved for autism, even though doctors currently treat autistic children with a huge arsenal of antipsychotics, antidepressants, and ADHD drugs. So what makes risperidone so special?

Frequently, risperidone does reduce autistic symptoms. It also works better than other psychotropic drugs (which is damning with faint praise). But let's look at what happens to kids who take Risperdal for longer than 56 days—the length of time the FDA thought sufficed to study the effects of a powerful drug on children as young as five. Here are just some of the potential dangers of this drug:

—***Type II diabetes.*** A new study (Lambert et al., 2006) reports that for schizophrenic patients, risperidone increases the risk of developing type II diabetes—a potentially deadly disease that can also lead to blindness or loss of limbs—by 60%.

—***Metabolic syndrome.*** "Metabolic syndrome" is a term doctors use for a combination of abdominal weight gain, bad cholesterol and triglyceride levels, high blood pressure, insulin resistance, and other unhealthy biochemical changes. It's a dangerous condition, because it puts people at risk for diabetes, heart disease, and stroke. Recent research (Yumru et al., 2006) showed that the risk for metabolic syndrome was significantly higher for a group of bipolar patients taking risperidone than for a similar group not taking this or similar "atypical antipsychotics."

—***Stroke in older patients.*** In 2003, the FDA ordered new warnings on risperidone and related drugs, to alert doctors to this risk.

—***Massive weight gain.*** Children and adults taking risperidone can experience huge weight gains over a short time—sometimes as much as 50 pounds in a few months.

—***Pituitary tumors.*** A recent study (see ARRI 19/3) identified 48 patients taking risperidone who developed benign pituitary tumors. The finding is consistent with the known association between risperidone and hyperprolactinemia, in which an excess of the pituitary hormone prolactin causes symptoms including breast milk secretion in males. (Pituitary tumors are one cause of hyperprolactinemia.)

Not scary enough? Other side effects of risperidone include nausea, dizziness, insomnia, anxiety, muscle stiffness or pain, low blood pressure, fever, confusion, irregular pulse, sweating, diarrhea, constipation, heartburn, stomach pain, agitation, seizures, weakness in an arm or leg, difficulty swallowing, rash, unusual bleeding or bruising, yellowing of the skin, increased salivation, and painful penile erection (which not only is dangerous but also can necessitate surgery). Like many other psychotropic drugs, risperidone can also cause tardive dyskinesia, a neurological disorder that result in uncontrolled movements of the mouth, face and trunk. And it occasionally causes neuroleptic malignant syndrome, in which the body "overheats" —sometimes fatally.

The risk/benefit question

Now, let's ask a logical question: given this huge list of unpleasant, dangerous, or even potentially fatal effects, does risperidone have an acceptable risk/benefit ratio?

On the Autism Research Institute's Form 34Q, we ask parents to rate the effects of drug and non-drug treatments on their autistic children's behavior. Risperidone indeed beats out other drug treatments: its better-to worse ratio is 3-to-1. (Ritalin, by comparison, has a ratio of 0.7-to-1, meaning that it more often does harm than good.)

But does that make risperidone a miracle drug? To see, let's put it up against popular autism treatments that don't involve psychotropic drugs, again using data from 34Q:

BETTER TO WORSE RATIO:	
Risperidone	3 to 1
Pepcid	3 to 1
Vitamin B6/Magnesium	10 to 1
Vitamin B12	15 to 1
Cod Liver Oil	16 to 1
Vitamin C	18 to 1
Digestive Enzymes	20 to 1
Zinc	20 to 1
Calcium	23 to 1
Wheat-free diet	29 to 1
Chelation	35 to 1

Those numbers would startle the FDA, if they bothered to look at them. Risperidone is at the bottom of the heap, scoring no better than the over-the-counter drug Pepcid when it comes to risks vs. benefits. Vitamins, other nutrients, and special diets leave risperidone in the dust.

And while it doesn't show in the statistics on 34Q, the improvements seen when parents use these treatments (particularly in the right combinations) is often amazing. At best, risperidone controls some symptoms, while creating others. Non-drug treatments, in contrast, can result in huge gains—and, in an increasing number of cases, even cures.

What's more, these treatments combine high effectiveness with a near-zero risk. In more than 20 studies of B6 with or without magnesium, for example, not a single serious side effect was reported. The one death associated with chelation turned out to be a medication error that had nothing to do with the proper treatment. And vitamins, minerals, omega-3 fatty acids, and healthful diets don't just safely ameliorate autistic symptoms —they also protect against heart disease, diabetes, cancer, and stroke.

Follow the money

What's behind the FDA's double standard—its rush to approve drugs like risperidone, while discouraging parents from trying safe non-drug approaches? Ask Dr. David Graham, the FDA whistle-blower who alerted the world to the dangers of Vioxx and suffered a campaign of intimidation and threats by the FDA as a result. He says, "As currently configured, the FDA is not able to adequately protect the American public. It's more interested in protecting the interests of industry. It views industry as its client, and the client is someone whose interest you represent."

The FDA protects the interests of drug manufacturers in two ways. The first is to approve drugs with little or no regard for their dangers or risk/benefit profiles, basing its decisions on dishonest drug company studies that inflate benefits and hide dangers. The second is to keep the drug companies' competition at bay, by treating nutritional therapies—and the consumers who use them—as "the enemy."

Thanks to Dr. Graham and a growing number of other FDA critics, Congress is finally beginning to take notice of the FDA's corruption. Given the flow of drug company money to both the FDA and politicians, however, it's naïve to expect real change. The best we can expect is that citizens, armed with information from the Internet and increasingly skeptical about the FDA and its drug-company cronies, will increasingly select treatments that help their children—not drug company executives.