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INTERNATIONAL MYOPIA PREVENTION ASSOCIATION

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Daniel G. Schultz: Director
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard, Suite 100
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Re: Docket No. 2005P-0166

I have received the letter of August 2, 2006 from your deputy, Linda S. Kahan, in which the FDA rejects my petition to require a warning to the public that prolonged close work is the cause of myopia and that minus lenses increase the rate of myopia development. The petition, your decision, and this letter are now available to the world on the Internet at www.myopia.org/fda.htm. Also at www.myopia.org, you will find the whole story about the myopia tragedy, including a similar brush-off letter I received from the National Eye Institute years ago when I sought their help in testing the Myopter further. Both letters show a similar lack of concern for human suffering.

It appears that you have spent 15 months thinking up every possible reason to do nothing, while hundreds of millions of children around the world continue to be made into visual cripples by tens of thousands of eye doctors. They do this because that's where the money is. This is the biggest consumer fraud in the history of the world; yet to you it is not worthy of any action. By this decision, the FDA has established itself as a major player in the worldwide conspiracy to hide the truth from the public.

I believe this is just another example of how the money of big business has corrupted our government, and the FDA is a shining example of putting business interests before public health. Are you solely responsible for this decision? Is the FDA Commissioner, Andrew von Eschenbach, orchestrating this tragedy? Or did it go as far as the Secretary of Health and Human Services, Mike Leavitt? It is difficult to believe that either of these two persons had the time to investigate this matter in depth. Or did the word come down from the White House that this petition should be squashed because the optical industry and doctors are big contributors to the Republican Party and they want it that way? Isn't that how our government works these days? The public has a right to know who actually made this decision and is hiding in the background.

The FDA has a history of doing the dirty work of optical interests. In the early 1990's, the FDA sent armed agents to raid the businesses of a few small vendors of pinhole glasses. These devices have been in use for centuries and were being sold via newspaper ads and even on the early Internet. The products were destroyed and the businesses closed down. This outrageous action was done under pressure from eye doctors and optical companies who didn't want the public to know about or have access to this inexpensive method of correcting vision. That is why such glasses are not offered in optical stores. Prescription lenses are much more profitable.

So, the FDA sent out armed goons who used violence to keep harmless pinhole glasses away from the public while it now refuses to lift a finger to even warn the public about the vision-destroying capability of minus lenses. This is just one of many shameful events in the FDA's history. If you want to refresh your memory, you can read about this at www.myopia.org/conspiracy.htm. Now, with the expansion of the Internet, such glasses can be bought from many sources, even overseas, and the FDA would have a tough task trying to suppress them any longer.

Working with a Pittsburgh optometrist, I was the first person to prove that myopia could be prevented and reversed. These results were included in my petition and published in my book, *The Myopia Myth*. We didn't need a fancy study and a million dollars. We just did what everyone in the business said couldn't be done. The National Eye Institute refused to assist in further studies, even though I sat across the table from Carl Kupfer, the NEI Director at that time, and pleaded for his assistance. Yet it will fund studies for things as "looking for the gene that causes myopia." This would be comical if it wasn't so tragic. The NEI pretends to look for an answer to the myopia problem, but it actually does everything in its power to hide the truth. It is run for the benefit of optical business interests, not for the benefit of the public. The children using the Myopter were examined by a qualified, well-respected optometrist using conventional refractive techniques. Yet, on page six you dismiss this study as "anecdotal." You don't even know the meaning of the word. You can find my disgusting experience with the NEI related on www.myopia.org/nei.htm.

Your brush-off reply is so full of lies, distortions and omissions that it would take far too long to deal with all of them. But here are a few obvious comments:

1. You say you refuse to require a warning on minus lenses or place any limitations on what doctors do. You say you don't have the authority. But you also refuse to alert the public in any way. There is nothing preventing you from holding a press conference and giving the public such information as:

A. Monkeys, with eyes just like ours, develop myopia when kept in a visual-confining environment, proving that prolonged accommodation causes myopia.

B. A study of Eskimos showed that over 60% of the children were myopic while their parents and grandparents were not. The reason was that the children had the benefit of compulsory education. Their parents and grand parents were illiterate. This proves that myopia is not inherited.

C. Hold the book or other viewed object as far away as possible.

D. Use adequate light to reduce accommodation.

E. Take a break from close work frequently and look into the distance.

F. Don't use minus lenses unless absolutely necessary, since they increase accommodation.

G. Allowing myopia to develop increases the risk of retinal detachment, macular degeneration and glaucoma.

H. Discuss with your doctor the possible use of plus lenses to prevent myopia.

2. On page one, you state that "we believe that the current regulations provide adequate assurance of the safety and effectiveness of these devices." But, there ARE NO regulations concerning minus lenses. Doctors can prescribe them without regulation. That is the problem. And how can you say that minus lenses are safe. What proof do you have? There is no such proof.

3. On page three, you state that enforcement action is the duty of the individual states. Yet the states say that the FDA is the proper place to deal with this matter. How convenient for both of you to be able to place the responsibility elsewhere and wash your hands of everything. You say you have no authority to "interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." But we are asking for a label just like those used with prescription drugs. Requiring a label with prescription drugs is not interfering with the practice of medicine. It is a safety warning to the public. The public needs to be informed about the danger of minus lenses as well.

4. On page four, you say you are supporting the use of drugs which are placed in the eyes daily to paralyze the accommodation. For one thing, these drugs are toxic. Secondly, how are these children going to read

without their accommodation? They will obviously need lenses with a +3 add. So why not just give them the plus lenses and omit the drugs? Thirdly, you claim there is no evidence that prolonged accommodation causes myopia. Then why are you supporting the use of these drugs? This whole approach is idiotic. You are talking out of both sides of your bureaucratic mouth.

5. On page five, you state that the "FDA is unaware of any large, multicenter trial that incorporates the recommendations you suggest." Of course you aren't. Neither am I. And there will never be such a study because optical interests would never let it get off the ground. Such a study would mean the death of the genetic theory of myopia development. That would threaten this multi-billion dollar industry. Even if such a study was done, it would be ignored by the eye doctors, just as they have ignored all of Francis Young's marvelous, pioneering research. If I were to bring you ten blind children and within 30 days have them all seeing again, would you dismiss what you see before your eyes because no multicenter trial had been done? Anyone can reverse acquired myopia within 30 days, just as I did. But there is absolutely no interest in doing so.

6. On page six, you mention a study that "provides evidence that under-correction of myopia may actually increase its progression." In other words, they claim that a beginning myope will become more myopic if minus lenses are not prescribed. That's idiotic. This asinine study has been quoted far and wide by defenders of the status quo, but it has been completely discredited. That you would even mention this "study" shows how superficial and slanted your analysis is. Why don't you state that "the findings may have been subject to bias", as you stated about the Hong Kong study and the Francis Young study?

7. On page six, you say, "Without corrective lenses, myopic children cannot see distant objects clearly and would be at a significant visual disadvantage in schools, sports, and other activities of daily life." No kidding! Don't you understand that this whole thing is about PREVENTING children from becoming myopic in the first place? And don't you understand that they will also be at somewhat of a visual disadvantage when they go blind from the effects of an abnormal growth of the eye, caused by minus lenses?

In summary, common sense and science seem to count for nothing in your world. You seem to think that the eye doctors will police themselves and do nothing wrong. Does the tobacco industry police itself, or does it do everything in its power to make our children addicted to tobacco products? The same thing is happening in the optical business. Children are being victimized and made into lifelong, addicted customers. Your letter is obviously a political decision that is designed to protect the multi-billion dollar profits of the eye doctors and the optical industry.

In short, both the FDA and the NEI act as if your salaries are paid by the optical industry, rather than by the taxpayers you are supposed to serve. What kind of monsters are you? How do you live with yourselves? What do you use for a conscience? If we lived in a just world, the officials at the FDA and NEI would be taken into court and charged with crimes against humanity.

Donald Rehm
President



cc.

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