Page 85 5 Thank you. My 6 name is Matt Kotsovolos. I had LASIK surgery 7 in 2006 using the current IntraLase Wavefront 8 technology. At the time of my LASIK, I was 9 the Chief Financial Officer at the Duke eye 10 Center in Durham, North Carolina. 11 My surgery was considered a success 12 based on my uncorrected visual acuity now 13 being 20/20. However, for the last two years 14 I have suffered from debilitating and 15 unremitting eye pain as a result of LASIK. 16 The public hears LASIK complication 17 rates quoted by the LASIK industry as ranging 18 from between one to three percent. What the 19 public doesn't know, because the LASIK 20 industry markets this surgery in a most 21 unethical way, is that the complication rate 22 is likely in the 20 to 30 percent range. Page 86 1 Data from the FDA clinical trials 2 for LASIK reveals that the FDA allows laser 3 manufacturers to hide complications such as 4 dry eyes and impaired night vision by 5 reporting these as, quote, "symptoms." The 6 overall percentage of patients reporting these 7 complications in the FDA trials is 8 approximately 20 percent. 9 In April 2007, researchers from 10 Ohio State University College of Optometry 11 published results from a review of FDA 12 clinical trials of the 12 lasers approved for 13 LASIK between 1998 and 2004, including newer 14 wavefront technology. They reported that six 15 months after LASIK, roughly 20 percent of 16 patients experienced worse or significantly 17 worse dry eyes, and six months after LASIK 18 roughly 15 percent experienced worse or 19 significantly worse night vision disturbances. 20 Recently, the LASIK industry has 21 hired a media consulting firm in its mass 22 circulated results of a global LASIK patient Page 87 1 satisfaction rate of 95.4 percent. The LASIK 2 industry wants the public to believe that a 3 high satisfaction rate indicates a low 4 complication rate. However, being satisfied 5 with one's visual outcome and being free of 6 complications are two entirely different 7 matters. 8 Dr. Leo Maquire once wrote the 9 following in an ophthalmology editorial: "The 10 kerato-refractive literature contains 11 disturbing examples of patients who have 12 visual handicaps that place themselves and 13 others at significant risk for nighttime 14 driving accidents, and yet they are happy with 15 their results." 16 One of the most perplexing cases of 17 patient satisfaction comes from a 2007 report 18 of a patient who developed bilateral ectasia, 19 a serious sight-threatening complication which 20 may require corneal transplantation, who was 21 reportedly satisfied with his surgery. 22 As illustrated, patients can suffer Page 88 1 significantly complications or "symptoms," and 2 still claim to be satisfied patients. Patient 3 satisfaction surveys in LASIK are guaranteed 4 to lead to skewed results and significant 5 false positive data. 6 In addition, there is enough 7 evidence for the FDA to investigate that shows 8 the effects of devastating and irreversible 9 physical complications from bad LASIK outcomes 10 often leads to clinical depression. 11 Clinical depression can lead to 12 suicidal ideation. The length between bad 13 LASIK outcomes and suicidal ideation is real. 14 The link is further evidenced by true stories 15 of LASIK patients taking their own lives and 16 leaving suicide notes behind that detail their 17 struggles due to debilitating post-LASIK 18 complications. 19 I have met plenty of people who are 20 depressed and considering suicide because of 21 complications that are currently buried in the 22 device labeling and classified as symptoms or Page 89 1 side effects. How is it that patients want to 2 commit suicide because of side effects? 3 Can the Panel before us today 4 explain this? Why was there no research into 5 what constitutes a symptom, and what 6 constitutes a complication? Was it so that 7 the LASIK industry could obtain approval for 8 medical devices that otherwise would never 9 have seen the light of day? 10 Patients do not want to continue to 11 exist as helpless victims with no solutions 12 and no voice. The LASIK industry wants to use 13 the upcoming quality of life study that will 14 not commence until

sometime in 2009 to stall 15 for an extended period of time. The time for 16 stalling is over. 17 I urge the FDA Advisory Panel to 18 recommend placing a moratorium on LASIK until 19 a proper comprehensive study of long term 20 LASIK patient complications and symptoms, 21 including clinical depression, is completed. 22 I ask the FDA to change the Page 90 1 labeling for lasers for LASIK once this 2 moratorium is lifted, to report dry eyes and 3 night vision disturbances as complications and 4 not symptoms. Both of these so called 5 symptoms can last for a patient's entire post- 6 LASIK lifetime. 7 Those who are familiar with the 8 phenomena of deep capture understand that over 9 time regulatory agencies end up being 10 controlled by the very industries they are 11 supposed to regulate. The FDA is now 12 controlled and works for the benefit of the 13 LASIK surgeons and LASIK manufacturers. 14 This is easily illustrated by an 15 ASCRS press release on April 7, 2008, a full 16 two weeks before today's hearing. In that 17 press release, the FDA stated that LASIK is 18 safe and effective. 19 Clearly, the fix is in. ASCRS 20 would not have issued such a -- 21 CHAIRPERSON WEISS: Can you please 22 start closing your remarks? Page 91 1 MR. KOTSOVOLOS: Yes, thank you. 2 Clearly, the fix is in. ASCRS would not have 3 issued such a press release, had they not 4 known in advance that the FDA was going to 5 dismiss -- 6 CHAIRPERSON WEISS: We are going on 7 to our next speaker, please. Thank you. 8 (Applause.)