

Page 165 2 Panel members, my name 3 is Roger Davis. I have a PhD in clinical 4 psychology with perhaps 20 publications, 5 including several co-authored books and 6 psychological tests. 7 Back in 2000 I served as Director 8 of Research for the Surgical Eyes Foundation, 9 now VRSN. I have communicated with about 300 10 patients with LASIK complications. Over 100 11 have told me that they have considered 12 suicide because of their LASIK. Perhaps 90 13 percent indicates some element of deception, 14 which then drives the development of post-15 traumatic stress, depression and suicidal 16 ideation. 17 While Director of Research, we 18 submitted a study on depression and suicidal 19 thoughts to a major refractive surgery 20 journal. Among 58 patients admitting suicidal 21 ideation, 83 percent stated they were told 22 they were a success by their surgeon. Page 166 1 In 115 patients who were severely 2 depressed, the number was 76 percent. 3 Interestingly, the single complication most 4 strongly associated with suicidal ideation was 5 dry eye syndrome, considered a side effect or 6 symptom. 7 My most important point here today 8 is that patients respond emotionally to their 9 total situation, not simply to their eyes. 10 With minor complications, they develop various 11 adjustment disorders. With severe 12 complications, however, they develop what I 13 have termed refractive surgery shock syndrome, 14 which includes major depression, suicidal 15 ideation and post-traumatic stress. 16 Suicidal patients pass through 17 several stages of inquiry. First, they ask 18 such questions as "Will I ever get my vision 19 and my life back? Why didn't they tell me 20 this could happen? Why didn't my informed 21 consent mention this? Why didn't my surgeon 22 tell me I could have more than one Page 167 1 complication?" 2 Eventually patients move on to ask 3 questions about their surgeon: "Why is my 4 surgeon telling me nothing is wrong with my 5 eyes? Why are my complaints not being 6 recorded in my medical chart? Is my surgeon 7 really as good as he was presented? What if 8 my surgeon really does not understand what is 9 wrong with my eyes? If my doctor doesn't 10 understand, will anyone understand?" 11 Eventually, patients find others 12 like themselves on the Internet, and now they 13 begin asking questions about the industry 14 itself: If LASIK is so safe, why are so many 15 other patients out there with complications? 16 Why are so many patients telling the same 17 story? How are they getting away with this? 18 Why doesn't the FDA step in and stop this? 19 Why don't honest doctors speak up about this? 20 Is it really all about money? Am I the 21 victim of a medical cover-up? 22 Obviously, every patient who thinks Page 168 1 about suicide following LASIK wants to get 2 away from their eyes. Beyond this, however, 3 there are individual differences. 4 Some individuals have traveled 5 widely looking for solutions. Since they have 6 done everything they could possibly do, for 7 them suicide seems like a rational option. 8 Here, suicidal thoughts express the desire to 9 be done with the journey. 10 Many individuals see themselves as 11 victims of a corrupt industry. They feel 12 powerless to help themselves or others. Here, 13 suicidal wishes express the desire not to be a 14 victim, simply to return to a world of 15 integrity, compassion and purity. 16 Some patients vacillate between 17 periods of crisis and exhaustion, living on 18 the bring, constantly in fear that their 19 vision is getting worse. They have no time 20 for anti-LASIK activism. Here, suicidal 21 wishes express the desire to escape the 22 anxiety and unpredictability of complications. Page 169 1 Some patients feel that no one 2 understands their situation, not their doctor, 3 not their family, not even other patients. 4 Suicidal wishes express the desire to have the 5 severity of their vision issues finally 6 appreciated. If I kill myself, someone will 7 finally understand how bad it was. 8 Some patients feel that they paid 9 to have their vision destroyed. Here, 10 suicidal thoughts express guilt at having 11 wasted one's potential as a human being. 12 In my experience, no

pre-existing 13 psychopathology is necessary for patients to 14 develop suicidal ideation post-LASIK. Decades 15 of psychological research has shown that 16 catastrophic injuries of all kinds produce a 17 period of prolonged psychological crisis and 18 adjustment. Why should catastrophic LASIK 19 injuries be any different? 20 I have not known perfectionism or 21 body dysmorphic disorder to play a role in 22 post-LASIK depression or suicide. Page 170 1 I ask that the upcoming FDA study 2 address psychological construct such as 3 deception and adequacy of informed consent in 4 existing patients, in a prospective study that 5 could decide the future of the industry. 6 Patients may have different experiences and a 7 higher standard of care. 8 Also, I suggest to the Panel that, 9 if the FDA wants to understand depression and 10 suicide post-LASIK, forget about satisfaction 11 surveys. If you want to understand suicidal 12 patients, study suicidal patients. You can 13 find as many as you want. 14 Finally, I ask the Panel to declare 15 a moratorium on the use of the excimer laser 16 for refractive surgery. Research connecting 17 complications to quality of life problems 18 provides the ethical basis for informed 19 consent. That research should have been done 20 10 years ago. 21 Because this research does not yet 22 exist, refractive surgery cannot be performed Page 171 1 ethically, whatever its satisfaction or 2 complication rate. Thank you.