

(The presentation was made by Glenn Hagele on behalf of Dr. Hartzok) 9 I am making the
10 statement on behalf of Dr. David Hartzok and 11 Barbara Berney, co-founders of the Vision
12 Surgery Rehab Network. 13 The Vision Surgery Rehab Network, 14 VSRN, is a 501(c)(3)
15 nonprofit organization 16 whose purpose is to help patients with 17 complications from any
18 surgery that alters the 19 refractive status of the eye. 20 The bulk of our work focuses on 21
22 LASIK patients. We define their condition as 23 refractive surgery syndrome, RSS, a complex,
24 chronic visual, psychological and 25 physiological symptoms following any surgery Page
32 1 that affects the refractive effects of the 2 eye. 3 This Panel must be prepared to hear 4
5 the extremes of two sides of an ongoing 6 argument, those who maintain that LASIK does 7
8 not generate depression and other 9 psychological issues versus those who argue 10
11 strenuously that their lives have been 12 irretrievably harmed. 13 VSRN believes that both
14 extremes 15 are at times disingenuous in their arguments 16 and unnecessarily defiant in their
17 perspective. It is our hope that the 18 definition of refractive surgery syndrome 19 and, in
20 particular, its psychological 21 components will be recognized and accepted by 22 the FDA,
23 and that this definition will be a 24 starting point toward dialogue between the two 25
26 perspectives. 27 Physical, physiological and 28 psychological symptoms following LASIK may
29 30 combine to produce varying degrees of RSS. A Page 33 1 common complaint of LASIK,
2 dry eye, may be 3 thought of as a physical symptom, dryness, 4 burning or pain, that may
5 have physiological 6 attributes relative to an inadequate tear 7 film, which creates a
8 psychological awareness 9 of reduced vision. 10 As a contributing factor to RSS, 11 physical
12 dryness can be an intractable 13 condition. The other end of the RSS spectrum 14 is less
15 tangible and leads to most of the 16 post-surgery frustrations. VSRN contends that 17 vision
18 as a perception is more complex than 19 LASIK advocates acknowledge. 20 Vision, as
21 described in so many 22 studies and post-operative accounts, 23 concentrates heavily on the
24 measurable optical 25 attributes of the eye's condition. While 26 knowledge of the refractive
27 components of the 28 eye has grown, there has been no proportionate 29 increase in
30 understanding how the alteration 31 of the eye's optical elements adversely affect 32
33 perception. Clearly, a broader perspective is Page 34 1 needed. 2 Vision abnormalities
3 induced by 4 LASIK are perceptual in a way that existing 5 technology cannot discern. LASIK
6 has elicited 7 the gamut of subjective response from euphoric 8 elation to panicked angst.
9 While newer 10 technology may be safer and more effective 11 than in the past, even today's
12 advanced 13 procedures can reduce visual quality. 14 Our world, our reality, is the 15
16 summation of all of our perceptions, vision 17 being the most powerful. VSRN's experience 18
19 with patients is that LASIK alters their 20 reality in ways that disrupt their sense of 21
22 normalcy and well-being. 23 LASIK is an elective procedure. It 24 is natural for providers to downplay
25 negative 26 outcomes, particularly when there is no 27 causative effect. 28 Too frequently,
29 patients' 30 frustrations are compounded by denial of the 31 complaints by surgeons and other
32 post-surgery Page 35 1 examiners. They begin to believe that denial 2 is systemic in the
3 industry and that their 4 doctors are uncaring. 5 Those feelings, combined with 6 aggressive
7 marketing and inadequate informed 8 consent agreements exacerbate the 9 psychological
10 aspects of RSS. Patients' 11 visual perceptions should be validated, not 12 denied. 13 The loss
14 of visual quality reduces 15 patients' overall sense of well-being and 16 leads to depression
17 and chronic anxiety. How 18 doctors manage LASIK problems is just as 19 critical to their
20 patients' recovery as the 21 optical outcome. Any sense of non-caring 22 creates additional
23 stress for the patient. 24 The visual complications of LASIK 25 suggest that certain properties
26 in curvatures 27 of the cornea are unique to the individual and 28 may not be subject to

generalized nomographic 21 approach. 22 Even Wavefront analysis, while Page 36 1 elegant and attractive, fails to guarantee a 2 satisfactory surgical result. Patients with 3 Wavefront customized surgeries regularly 4 contact VSRN for help with RSS. 5 Rigid gas permeable contact lenses 6 and additional surgeries are the most common 7 rehab options. Informed consent agreements 8 fail to mention that neither is consistently 9 satisfactory nor successful. Patients whose 10 rehab efforts fail to restore normal vision 11 suffer a proportionately higher degree of RSS. 12 The number of patients affected is 13 incalculable, since successful LASIK, in the 14 surgeon's view, is procedural -- you are 20/20 15 -- while success of LASIK in the patient's 16 view is perceptual -- but it's not clear. 17 RSS will continue to remain under 18 reported until the doctor versus patient 19 discrepancy is resolved. VSRN believes that 20 refractive surgery syndrome results in quality 21 of life issues for a significant but unknown 22 number of patients. Page 37 1 Any meaningful investigation of the 2 quality of life after LASIK must be impartial, 3 undertaken by behavioral and perceptual 4 specialists with no vested interest in the 5 outcome. Thank you. 6 Those are the words of Barbara 7 Berney and David Hartzog.