[redacted]
10/6,7,8,13,14,15,20
22,23,26,27,30-
11/2/98 RALS

Patient [redacted] was diagnosed with hyperopia on August 3, 1998 and scheduled for left hyperopic [redacted] surgery on August 18, 1998 **EXHIBIT #60.** Patient [redacted] received left hyperopic [redacted] surgery on August 18, 1998 at the [redacted] by [redacted] **EXHIBIT # 61 & 62.**

After he read this observation I asked [redacted] if he had an excimer laser in his [redacted]. He stated yes, there is an excimer laser in that office but he does not own it. He went on to explain, it was a legal laser by [redacted] which could be bought on the open market and used at his discretion. According to [redacted] the laser is actually owned by a group out of New York and was acquired through a broker.

A fee is paid to the owner each time [redacted] uses the laser via a card that is inserted into the laser to record the number of uses. [redacted] asked why is the FDA interested in what he does with a legal laser? The only laser the FDA should be concerned with is the one at his [redacted] He stated that he should not be constrained by the agency to only perform laser eye surgery with the one laser just because it is listed in the IDE when you (FDA) don't have jurisdiction over the legal [redacted] laser in the [redacted] He also stated that [redacted] told him to use the Laser in the [redacted] if he had to perform hyperopic [redacted] enhancements on any of his patients.

I stated to [redacted] that patients [redacted] and [redacted] are enrolled in the clinical study [redacted] by virtue of their signatures on the patient information and consent forms, subsequent myopic [redacted] surgery with the indicated laser and at the location specified in the protocol. The clinical investigator should not perform a [redacted] procedure that is not specified in the protocol on an unindicated laser at an unidentified location on patients enrolled in the clinical study [redacted].

7. There was no documentation to show that the [redacted] notified the IRB about all amendments, changes or significant deviations to the protocol [per IRB requirements]

[redacted] is the Institutional Review Board [redacted] IRB) that is used by [redacted] to oversee the IDE clinical study, [redacted]