ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT
In the Matter of Health Discovery Corporation, File No. 132 3211

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order as to Health Discovery Corporation (hereafter "the company").

The proposed consent order ("proposed order") has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed order and the comments received, and will decide whether it should withdraw or make final the agreement's proposed order.

This matter involves the company's advertising for the MelApp mobile device software application. The Commission's complaint alleges that the company violated Sections 5(a) and 12 of the Federal Trade Commission Act by representing that MelApp accurately analyses moles and other skin lesions for melanoma and increases consumers' chances of detecting melanoma in early stages, because such claims were false or misleading, or were not substantiated at the time the representations were made. The complaint also alleges that the company violated Sections 5(a) and 12 by making the false or misleading representation that scientific testing proves that MelApp accurately detects melanoma.

The proposed order includes injunctive relief that prohibits these alleged violations and fences in similar and related violations. The proposed order covers any Device, as the term is used within the meaning of Sections 12 and 15 of the FTC Act, 15 U.S.C. §§ 52, 55. As additional fencing-in relief, the proposed order requires the company to follow appropriate recordkeeping and compliance reporting requirements, as well as document preservation requirements for human clinical studies that it conducts or sponsors on the Device.

Part I prohibits any representation that a Device detects or diagnoses melanoma or risk factors of melanoma, or increases users' chances of detecting melanoma in early stages, unless it is non-misleading and supported by competent and reliable scientific evidence. Such evidence must consist of human clinical testing of the Device that is sufficient in quality and quantity, based on standards generally accepted by experts in the field, is blinded, conforms to actual use conditions, includes a representative range of skin lesions, and is conducted by researchers qualified by training and experience to conduct such testing. In addition, the company must maintain all underlying or supporting data that experts in the relevant field generally would accept as relevant to an assessment of such testing.