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.

Part II prohibits any representation about the health benefits or health efficacy of a Device, unless it is non-misleading and supported by competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant

and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Part, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted by a qualified person in an objective manner and are generally accepted in the profession to yield accurate and reliable results. When that evidence consists of a human clinical trial, the company must maintain all underlying or supporting data and documents that experts in the relevant field generally would accept as relevant to an assessment of such testing.

Part III, triggered when the human clinical testing requirement in Parts I or II applies, requires the company to secure and preserve all underlying or supporting data and documents generally accepted by experts in the relevant field as relevant to an assessment of the test, such as protocols, instructions, participant-specific data, statistical analyses, and contracts with the test's researchers. There is an exception for a "Reliably Reported" test, defined as a test that is published in a peer-reviewed journal and that was not conducted, controlled, or sponsored by any proposed respondent or supplier. Also, the published report must provide sufficient information about the test for experts in the relevant field to assess the reliability of the results.

Part IV prohibits the company from misrepresenting, including through the use of a product or service name, endorsement, depiction, or illustration, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, or that any benefits of such product or service are scientifically proven, including, but not limited to, that studies, research, testing, or trials prove that a product or service detects or diagnoses a disease or the risks of a disease.

Part V provides the company will pay an equitable monetary payment of Seventeen Thousand Six Hundred Ninety-three Dollars ($17,693).

Part VI contains recordkeeping requirements for advertisements and substantiation relevant to representations covered by Parts I through III, as well as order receipts covered by Part VII.

Parts VII through IX require the company to deliver a copy of the order to officers, employees, and representatives having managerial responsibilities with respect to the order's subject matter, notify the Commission of changes in corporate structure that might affect compliance obligations, and file compliance reports with the Commission.

Part X provides that, with exceptions, the order will terminate in twenty years.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the complaint or proposed order, or to modify the proposed order's terms in any way.