

adequate substantiation, that testimonials from consumers appearing in the ads reflect the typical or ordinary experience of people who have used the product.

The complaint also alleges that respondent falsely represented that scientific studies demonstrate that the Slimming Insoles cause significant weight loss without changes in diet or exercise. In addition, the complaint alleges that respondent falsely represented that an organization named Advanced Bio/Natural Research Labs is a bona fide, independent research organization that has published a report containing the results of valid, independent testing of the Slimming Insoles.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent respondent from engaging in similar acts and practices in the future.

Part I of the order requires respondent to possess competent and reliable scientific evidence to support any claim that any product causes weight loss, with or without changes in diet or exercise, or provides any weight loss, fat loss, weight regulation, weight control or weight maintenance benefit. Part II prohibits respondent from using the name "Slimming Insoles" or any other name in a manner that represents that any product causes weight loss, unless respondent possesses competent and reliable scientific evidence that substantiates the representation.

Part III prohibits respondent from claiming that the experience represented in any user-testimonial or endorsement of any food, dietary supplement, drug, device, or weight loss product or program represents the typical or ordinary experience of members of the public who use the product, unless, at the time, respondent possesses and relies upon competent and reliable scientific evidence substantiating the representation or respondent discloses, clearly and prominently, and in close proximity to the testimonial or endorsement, what the generally expected results would be or that consumers should not expect to experience similar results.

Part IV prohibits respondent from representing that Advance Bio/Natural Research Labs is a bona fide, independent research organization or that it has published a report containing the results of valid, independent testing of any product. Part V prohibits, in connection with the sale of any food, dietary supplement, drug, device or weight loss product or program, misrepresentations of the existence, contents, validity, results, conclusions

or interpretations of any test, study or research or the existence, nature, purpose or activities of any organization.

Part VI requires respondent to deposit \$40,000 into an escrow account, which will be used by the Commission to provide either direct redress to purchasers of the Slimming Insoles or will be paid to the United States Treasury, if the Commission determines that direct redress to consumers is wholly or partially impracticable. The order suspends the full \$40,000 liability, however, provided that respondent pays \$7,500 to the Commission no later than the date the order becomes final. The full \$40,000 becomes due, however, should respondent default in making the \$7,500 payment. In addition, the Commission's acceptance of the order is expressly premised upon financial statements and related documents provided by the respondent, and the Commission reserves the right to re-open the proceeding to determine if the financial information provided by respondent contains any material misrepresentations or omissions. If the Commission determines that there are any material misrepresentations or omissions in the financial information provided, then the full \$40,000 becomes due and payable.

Parts VII through X relate to respondent's obligations to maintain and make available to the Commission certain records; to provide copies of the order to respondent's personnel; to notify the Commission of changes in corporate structure; and to file compliance reports with the Commission. Part XI provides that the order will terminate after twenty years, under certain circumstances.

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 agreement and proposed order or to modify in any way their terms.

Donald S. Clark,

Secretary.

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FEDERAL TRADE COMMISSION

[File No. 942-3237]

KCD Holdings, Inc., et al.; Interactive Medical Technologies, Ltd., et al.; William Pelzer, Jr.; and William E. Shell, M.D.; Analysis to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreements.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair or deceptive acts or practices and unfair methods of competition, the four consent agreements, accepted subject to final Commission approval, would prohibit, among other things, the California-based companies, which market cellulose-bile products, and their officers from providing means and instrumentalities or substantial assistance to any person who they know, or should know, is making any false or unsubstantiated benefit, performance, efficacy or safety claim for any weight loss, fat or cholesterol reduction product or program. The consent agreements would require KCD, KCD Holdings and Richards to pay \$150,000 in consumer redress, in thirteen installments over a period of one year, Interactive Medical and Effective Health to pay \$35,000 in consumer redress, and Dr. William E. Shell, a former officer of Interactive Medical Technologies, Ltd., to pay \$20,000 in consumer redress.

DATES: Comments must be received on or before June 6, 1997.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 6th St. and Pa. Ave., N.W., Washington, D.C. 20580.

FOR FURTHER INFORMATION CONTACT: Laureen France or Nadine Samter, Federal Trade Commission, Seattle Regional Office, 915 Second Ave., Suite 2896, Seattle, WA. 98174. (202) 220-6350 or 220-4471.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and Section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the above-captioned consent agreements containing a consent orders to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, have been placed on the public record for a period of sixty (60) days. The following Analysis to Aid Public Comment describes the terms of the consent agreements, and the allegations in the complaints. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home page (for March 25, 1997), on the World Wide Web, at "http://www.ftc.gov/os/actions/htm." A paper copy can be obtained from the FTC Public Reference Room, Room H-130, Sixth Street and Pennsylvania Avenue, N.W., Washington, D.C. 20580, either in person or by calling (202) 326-3627. Public comment is invited. Such comments or views will be considered

by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Orders

The Federal Trade Commission ("Commission") has accepted, subject to final approval, agreements to proposed consent orders from KCD, Incorporated ("KCD") and KCD Holdings, Inc. ("KCD Holdings"), their former officer, Clark M. Holcomb ("Holcomb"), and their current officer, Bonnie L. Richards ("Richards") (hereinafter "KCD respondents"), their advertising agency Deerfield Corporation ("Deerfield"), and its owner, Gerald E. Hatto ("Hatto"). The KCD respondents market and sell an over-the-counter weight loss product, known as SeQuester, comprised of fiber and ox bile. The product advertisements have represented that the product reduces the body's absorption of fat and sugar from consumed food, thereby providing weight loss and cholesterol lowering benefits. Respondents Deerfield and Hatto assisted in the creation and dissemination of the SeQuester advertisements.

The Commission has also accepted, subject to final approval, agreements to proposed consent orders from Interactive Medical Technologies, Ltd. ("IMT"), its wholly owned subsidiary, Effective Health, Inc. ("EHI"), William Pelzer, Jr. ("Pelzer"), a former officer of IMT and EHI, and William E. Shell, M.D. ("Shell"), also a former officer of IMT (hereinafter "IMT respondents"). These respondents marketed and sold an over-the-counter weight loss product, known as Lipitrol, also comprised of fiber and ox bile. The Lipitrol product advertisements represented that the product reduced the body's absorption of fat from consumed food, thereby providing weight loss and cholesterol lowering benefits. The IMT respondents also provided means and instrumentalities or substantial assistance to the KCD respondents' marketing and sale of SeQuester.

The proposed consent orders have been placed on the public record for sixty (60) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreements and the comments received and will decide whether it should withdraw from the agreements and take other appropriate action or make final the proposed orders contained in the agreements.

The Proposed Complaints

The Commission's complaint against the KCD respondents, Deerfield and Hatto, charges these respondents with making false and unsubstantiated claims, in advertising and promotional materials, regarding the efficacy of SeQuester as a weight loss, fat reduction and cholesterol reduction product. Specifically, the complaint alleges that the KCD respondents falsely represented, expressly or by implication, that SeQuester prevents or significantly reduces the body's absorption of fat and sugar from consumed food. The complaint also charges that these respondents failed to possess and rely upon a reasonable basis for these representations. The Complaint further alleges that these respondents made false and deceptive representations that scientific research demonstrates that SeQuester prevents or significantly reduces the body's absorption of fat from consumed food and causes significant weight loss.

In addition, the complaint alleges that the KCD respondents have represented that SeQuester causes significant weight loss; allows consumers to eat high-fat foods without gaining weight; causes significantly greater weight loss than diet and exercise alone; allows consumers to eat high-fat foods without increasing their risk of high cholesterol, clogged arteries, heart disease and other health problems associated with a high-fat diet; reduces the risk of high cholesterol, clogged arteries, heart disease and other problems associated with a high-fat diet; and is beneficial and safe when used in amounts sufficient to cause diarrhea. The Complaint charges that these respondents did not possess and rely upon a reasonable basis for these representations.

The complaint also alleges that Deerfield and Hatto have represented, expressly or by implication, that SeQuester causes significant weight loss; allows consumers to eat high-fat foods without gaining weight; allows consumers to eat high-fat foods without increasing their risk of high cholesterol, clogged arteries, heart disease and other health problems associated with a high-fat diet; prevents or significantly reduces the body's absorption of fat and sugar from consumed food; reduces the risk of high cholesterol, clogged arteries, heart disease and other problems associated with a high-fat diet; and significantly reduces the body's absorption of sugar from consumed food. The complaint charges that Deerfield and Hatto did not possess and rely upon a reasonable basis for these

representations. The complaint further alleges that Deerfield and Hatto falsely represented that scientific research demonstrates that SeQuester prevents or significantly reduces the body's absorption of fat from consumed food and causes significant weight loss. The complaint also charges that respondents Deerfield and Hatto knew or should have known that these representations were false and misleading.

The Commission's complaint against the IMT respondents charges IMT, EHI and Shell, with making false and unsubstantiated advertising claims regarding the efficacy of Lipitrol as a weight loss, fat reduction and cholesterol reduction product. Specifically, the complaint alleges that IMT, EHI and Shell falsely represented, either expressly or by implication, that Lipitrol prevents or significantly reduces the body's absorption of fat from consumed food, and absorbs approximately 5.9 grams of fat per tablet from consumed food. The complaint also charges that respondents IMT, EHI and Shell failed to possess and rely upon a reasonable basis for these representations. The complaint further alleges that these respondents made false and deceptive representations that scientific research demonstrates that Lipitrol prevents or significantly reduces the body's absorption of fat from consumed food, absorbs approximately 5.9 grams of fat per tablet from consumed food, causes significant weight loss and lowers blood cholesterol levels.

In addition, the complaint alleges that respondents IMT, EHI and Shell have represented that Lipitrol causes significant weight loss; lowers blood cholesterol levels; reduces, or reduces the risks associated with, high cholesterol, including clogged arteries, high blood pressure, diabetes, breast cancer and heart disease; causes significantly greater weight loss than diet and exercise alone; and is beneficial and safe when taken in amounts sufficient to cause diarrhea. The complaint charges that these respondents did not possess and rely upon a reasonable basis for these representations.

Respondent William Pelzer, Jr. in not included in the above-mentioned allegations because he had no involvement in the advertising, marketing or sale of Lipitrol.

In addition, the complaint charges that the IMT respondents, including respondent Pelzer, provided means and instrumentalities and/or substantial assistance to others who respondents knew or should have known were making false and deceptive or

unsubstantiated claims for the product, sold under the name SeQuester. Specifically, the complaint alleges that the respondents licensed to KCD, its holding company, KCD Holdings, those companies' former principal, Holcomb, and current principal, Richards, the exclusive rights to market the product.

The complaint alleges that the IMT respondents knew or should have known that the KCD respondents made false and deceptive or unsubstantiated representations similar to those made for Lipitrol, in advertisements for SeQuester. The complaint charges that despite the fact that respondents knew or should have known that KCD was making the false and deceptive, and/or unsubstantiated representations in the marketing and sale of SeQuester, the IMT respondents nevertheless provided various services and promotional materials to the KCD respondents in furtherance of the KCD respondents' efforts to disseminate these false claims, including providing the KCD respondents with studies purporting to show that SeQuester effectively reduces the body's absorption of fat from consumed food and causes significant weight loss; the licensing rights to market and sell the product to consumers; technical information regarding the product; and various promotional materials and information for marketing the product.

The Proposed Orders

The Commission has accepted four separate consent orders in this matter. The proposed orders contain provisions designed to remedy the alleged violations. The proposed orders against respondents KCD Holdings, Inc., KCD, Incorporated and Bonnie L. Richards; IMT and EHI; and Shell provide for the payment of consumer redress in installments over a period of one year from the date the proposed orders become final. In the event that consumer redress is not feasible, the proposed orders provide that the funds will be deposited in the United States Treasury. In addition, the proposed order against respondent Shell requires him to post a performance bond of either \$250,000 or \$1,000,000, depending on the circumstances of his activities.

Proposed Consent Order with the KCD Respondents, Deerfield and Hatto

Part I of the proposed consent order against the KCD respondents, Deerfield and Hatto bars them from making representations that SeQueter or any product or program prevents or reduces the body's absorption of fat or sugar from consumed food unless the

representation is true at the time it is made and is supported by competent and reliable scientific evidence.

Part II of the proposed consent order against the KCD respondents, Deerfield and Hatto prohibits them from representing that SeQueter or any product or program provides any weight loss benefit; causes greater loss of body fat than diet and exercise alone; allows consumers to eat high-fat foods without increasing their risk of high cholesterol, clogged arteries, heart disease or other health problems associated with a high-fat diet; or reduces, or reduces the risk of, high cholesterol, clogged arteries, heart disease and other health problems associated with a high-fat diet, unless respondents can substantiate these representations with competent and reliable scientific evidence.

Part III of the proposed consent order against the KCD respondents prevents them from representing that SeQueter or any product or program can be used beneficially and safely, in amounts or with frequency sufficient to cause diarrhea, unless, at the time the representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates the representation, which when appropriate, must be competent and reliable scientific evidence.

Part IV of the proposed consent order against the KCD respondents, Deerfield and Hatto bars them from misrepresenting the existence, contents, validity, results, conclusions or interpretations of any test, study or research.

Part V of the proposed consent order against the KCD respondents, Deerfield and Hatto prohibits them from making representations about the benefits, performance, efficacy or safety of SeQueter or any product or program unless competent and reliable evidence substantiates any such representation.

Part VI of the proposed consent order against the KCD respondents provides Deerfield and Hatto with a defense to Parts I, II and V of the order if they neither knew nor had reason to know of an inadequacy of substantiation for any representation covered by those parts of the order; and a defense to Part IV of the order if they neither knew nor had reason to know that the test, study or research did not prove, demonstrate or confirm any representation covered by that part of the order.

Part VII of the proposed order against the KCD respondents requires KCD, KCD Holdings and Richards to pay \$150,000 in consumer redress, in thirteen installments over a period of one year. If consumer redress is impracticable, Part VII provides that

these funds will be paid to the United States Treasury. Part VII(C) requires KCD, KCD Holdings and Richards to provide the Commission with a security interest in certain property to insure full payment of the \$150,000 of consumer redress.

Parts VIII and IX of the proposed order against the KCD respondents, Deerfield and Hatto contain provisions permitting certain claims that are approved for labeling by the FDA, either under the Nutrition Labeling and Education Act, a tentative final or final monograph or under any new drug application approved by the FDA.

Parts X, XI, XII, XIII and XIV of the proposed order against the KCD respondents, Deerfield and Hatto contain compliance reporting provisions requiring respondents to: retain records that bear on their compliance with the order; distribute copies of the order to those persons having responsibility with respect to the subject matter of the order; notify the Commission of any changes in the structure of the corporate respondents that may affect their compliance obligations under the order, or any changes in the business affiliations of the individual respondents; and report to the Commission their compliance with the terms of the order.

Part XV of the proposed order against the KCD respondents, Deerfield and Hatto contains a provision automatically terminating the order twenty (20) years from the date that it becomes final.

Proposed Consent Order With IMT, EHI, Shell and Pelzer

Part I of the proposed consent order against respondents IMT and EHI bars them from making representations that LIPITROL or any weight loss, fat reduction or cholesterol reduction product or program prevents or reduces the body's absorption of fat from consumed food or absorbs any amount of fat from consumed food unless the representation is true and supported by competent and reliable scientific evidence. Part I of the proposed order against respondent Shell contains the same bar, but covers representations for Lipitrol or any product or program.

Part II of the proposed order against respondents IMT and EHI prohibits them from representing that Lipitrol or any weight loss, fat reduction or cholesterol reduction product or program, or any food, drug or dietary supplement, provides any weight loss benefit; lowers blood cholesterol levels; reduces, or reduces the risks associated with, high cholesterol, including clogged arteries, high blood pressure, diabetes, breast cancer and heart

disease; or can be used, beneficially and safely, in amounts or with frequency sufficient to cause diarrhea, unless respondents can substantiate these representations with competent and reliable scientific evidence. Again, the same prohibition is contained in Part II of the proposed order against respondent Shell, but covers representations for Lipitrol or any product or program.

Part III of the proposed order against respondents IMT and EHI prohibits them from misrepresenting the existence, contents, validity, results, conclusions or interpretations of any test, study or research in connection with Lipitrol or any weight loss, fat reduction or cholesterol reduction product or program, or any food, drug or dietary supplement. Part IV of the proposed order prohibits respondents IMT and EHI from making representations about the benefits, performance, efficacy or safety of Lipitrol or any weight loss, fat reduction or cholesterol reduction product or program, or any food, drug or dietary supplement unless competent and reliable scientific evidence substantiates any such representation. Parts III and IV of the proposed order against respondent Shell are the same except that the prohibitions apply to representations for Lipitrol or any product or program.

Part V of the proposed orders against respondents IMT, EHI and Shell, and Part I of the proposed order against respondent Pelzer, bars each of these respondents from providing means and instrumentalities or substantial assistance or support to any person or entity who they know or should know is making any false or misleading or unsubstantiated claim for any weight loss, fat reduction or cholesterol reduction product or program. The proposed orders define "assistance" to include providing: tests, analyses, studies or research to determine the benefits, performance, efficacy or safety of the product or program; licensing or other contractual rights to market any such product or program; technical assistance; or advertising, labeling or promotional materials for the marketing and sale of any such product or program.

Part VI of the proposed orders against respondents IMT, EHI and Shell, and Part II of the proposed order against respondent Pelzer, require these respondents to monitor business practices of certain parties to whom they provide assistance. To the extent that any such party is engaged in the marketing and sale of any weight loss, fat reduction or cholesterol reduction

product or program, these respondents must make an effort to determine whether false or misleading or unsubstantiated claims are being made with respect to any such product or program. Specifically, these respondents must review all advertisements and promotional materials and all tests, reports, studies, surveys, demonstrations or other evidence that any such person relies upon in making any claims to consumers. In addition, these respondents are required to terminate their business relationship with any person whom they know or should know is making any false or misleading or unsubstantiated claims.

Part VII of the proposed order against respondents IMT and EHI requires them to pay \$35,000 in consumer redress in three installments over a period of one year. If consumer redress is impracticable, Part VII provides that these funds will be paid into the United States Treasury. Part VII(C) requires IMT and EHI to provide the Commission with a security interest in certain property to insure full payment of the \$35,000 of consumer redress.

Part VII(A)(1) and (2) of the proposed order against respondent Shell requires him to obtain a performance bond for \$1,000,000 before he markets, sells or holds any ownership interest or official position in any business that advertises or sells Lipitrol or any other weight loss, fat reduction or cholesterol reduction product composed of fiber and bile extract. Part VII(A)(3) and (4) of the proposed order also requires respondent Shell to obtain a performance bond of \$250,000 before he markets, sells or holds an ownership interest or official position in any business that advertises or sells any weight loss, fat reduction or cholesterol reduction product or program to consumers, other than his treatment of patients in connection with his private medical practice. Parts VII(B) through (F) require respondent Shell to provide a copy of the bond to the FTC; prohibit him from disclosing the existence of the bond to any consumer; and describe the period during which the bond must remain effective, the bond's coverage, the bond's potential beneficiaries and certain other administrative requirements.

Part VIII of the proposed order against respondent Shell requires him to pay consumer redress in the amount \$20,000 in four installments over a period of one year. In the event that consumer redress is impractical, this Part provides that these funds will be paid into the United States Treasury. Part VII(C) requires Shell to provide the Commission with a security interest in certain property to

insure full payment of the \$20,000 of consumer redress.

Parts VIII and IX of the proposed order against respondents IMT and EHI, Parts IX and X of the proposed order against respondent Pelzer, contain provisions permitting certain claims that are approved for labels by the FDA, either under the Nutrition Labeling and Education Act, a tentative final or final monograph or under a new drug application approved by the FDA.

Parts X, XI, XII and XIII of the proposed order against respondents IMT and EHI, Parts XI, XII, XIII and XIV of the proposed order against respondent Shell, and Parts V, VI, VII and VIII of the proposed order against respondent Pelzer, contain compliance reporting provisions requiring these respondents to: retain all records that would bear on their compliance with the respective orders; notify the Commission of any changes in the structure of the corporate respondents that may affect their compliance obligations under the orders, or any changes in the business affiliations of the individual respondents relating to the advertising, offering for sale, sale or distribution of any weight loss, fat reduction or cholesterol reduction product or program; distribute copies of the orders to those persons having responsibility with respect to the subject matter of the respective orders; and report to the Commission their compliance with the terms of the respective orders.

Part XIV of the proposed order against respondents IMT and EHI, Part XV of the proposed order against respondent Shell, and Part IX of the proposed order against respondent Pelzer contain a provision automatically terminating the order twenty (20) years from the date that they become final.

The purpose of this analysis is to facilitate public comment on the proposed orders. It is not intended to constitute an official interpretation of the agreements and proposed orders or to modify their terms in any way.

Donald S. Clark,

Secretary.

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GENERAL ACCOUNTING OFFICE

Federal Accounting Standards Advisory Board Meeting

AGENCY: General Accounting Office.

ACTION: Notice of meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. No. 92-463), as amended,