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June 23, 1998

## AMA denies permitting insurance reimbursement for CCSI.

Chromatics Color Sciences International, Inc. (OTC: CCSI) (Price: \$7.25) announced in a press release dated March 16, 1998 that it had "received a letter from the American Medical Association permitting 3rd party insurance reimbursement in all U.S. states for each use of the Company's non-invasive device under AMA Code CPT 82250, which is the same reimbursement code for the laboratory blood test currently used to monitor hyperbilirubinemia." The information below proves that these statements are both purposefully misleading and untrue.

In 1966 the American Medical Association ("AMA") began publishing its Current Procedural Terminology ("CPT") book. This book is a listing and coding of procedures and services performed by physicians and other health care professionals. Each procedure and service is assigned a short and long description and a five-digit code.

The use of the CPT codes provides a common language and simplifies the reporting of services. The CPT codes are used by physicians, hospitals and insurance companies. The CPT codes are used for billing, quantification of the use of specific procedures and medical education. According to the AMA, the CPT is the most commonly used system for documenting services.

It is stated on the Introduction page of CPT that "Inclusion in CPT does not represent endorsement by the American Medical Association of any particular diagnostic or therapeutic procedure. Inclusion or exclusion of a procedure does not imply any health insurance coverage or reimbursement policy".

In 1983 the Health Care Financing Administration (HCFA) agreed to use CPT as part of its Common Procedure Coding System to assist in the assignment of reimbursement amounts. An increasing number of managed care and other third-party insurance companies base their reimbursement policies on the values established by HCFA. However, insurance companies and other third-party payers are not obligated to accept CPT codes to describe treatment nor are they obligated to pay for services described in the CPT book.

Each insurance company is solely responsible for its own reimbursement policies. The insurance industry uses the CPT book to simplify the processing of claims. Insurance companies individually determine the amount of money they are willing to reimburse for each coded procedure or service.

The AMA has no record of any letter sent by the AMA to Chromatics allowing it to claim the AMA is permitting third party insurance reimbursement in all U.S. states for each use of its Colormate III. In fact, the AMA has no record of any letter having been sent to Chromatics.

According to the American Medical Association's Department of Coding and Nomenclature, on February 5, 1998 a woman identifying herself as "a research consultant" requested the CPT code and general information for a "neo-natal quantitative bilirubin test." The AMA informed us that the consultant gave no indication that she was working on behalf of Chromatics. She did not mention any specific products in her inquiries. She also failed to mention that she was researching a non-invasive test used to "estimate" total bilirubin. The AMA told us that when they contacted Chromatics after the press release to identify the person to whom they had supposedly written the letter, Chromatics

stated that it had been one of four consultants used by the company.

Upon review of the Chromatics press release the AMA informed us that they believe it contains false information and falsely implies an AMA endorsement. CPT code 82250 represents the laboratory blood test used for monitoring hyperbilirubinemia. The AMA never recommended the CPT code 82250 for Chromatics' device.

The AMA subsequently contacted Chromatics requesting information about their test. Since learning that it is non-invasive, the AMA is not recommending code 82250 for this product. The test has currently been given a "miscellaneous code" 84999, which represents all unlisted chemistry procedures. The earliest possible review of a proposal for the addition of a code specific to a non-invasive procedure to estimate total bilirubin would be in November 1998. No proposal has been made for a new code.

Chromatics now admits that it "never considered" Colormate III instrument sales "to be the major income potential for this market". Apparently, this led Chromatics to create the need for a disposable attachment. Chromatics claims that its Colormate III "requires a proprietary disposable calibration standard which is used for each test performed to prevent cross contamination between patients and ensure the accuracy of each reading". This means that the Colormate III needs to be recalibrated or checked after each use and requires physical contact with the patient to eliminate external light in order to work.

It is absurd to claim that a color measurement instrument would require calibration after each use. It is equally as absurd to claim that a test based on light that should not require skin contact can cause any contamination. Colorimeters that do not require skin contact or calibration after each use are easily obtainable. This makes Chromatics' device crude and its "disposable" completely unnecessary.

The potential price of any disposable would have to be insignificant. Chromatics repeatedly states that hospitals charge \$22 to \$34 for a bilirubin blood test. These tests are simple, use only a drop of blood, are relatively painless and are processed by large, continuous low variable cost in-hospital laboratory instruments. Furthermore, the test costs the hospital less then \$1. The amount that hospitals charge and third-party insurers are willing to reimburse for performing necessary laboratory bilirubin blood test (CPT code 82250) bears no relationship to any amount that hospitals would pay for a disposable item related to a non-invasive "estimating" device.

Chromatics' non-invasive bilirubinometer uses a standard, industrial colorimeter. Estimating the level of serum bilirubin using the yellow content of a baby's skin color is a routine procedure that does not require any new technology. Our review of the medical literature on the use of non-invasive transcutaneous bilirubinometers to detect and monitor hyperbilirubinemia in newborns found at least 121 different studies. These devices were tested on babies of different races, ages and under at least twenty different conditions. All of these devices provided more accurate estimates of bilirubin levels than a physician's visual assessment. However, these devices and the Colormate III cannot be used to determine and legally document exact bilirubin blood levels.

The world bilirubinometer market is less than \$2.5 million. Non-invasive bilirubinometers are unnecessary and cannot replace blood testing. Non-invasive bilirubinometers are simple, inexpensive devices that do not require any new technology. Therefore, the world non-invasive bilirubinometer market, if it ever develops, will be highly competitive and insignificant.

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