COMMENTARY REGARDING ARTICLE ON QUACKWATCH ABOUT CCR / CMRT By
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Several matters should be clarified before providing specific comment on the text from the Quackwatch website.

1. It was my privilege to invent and develop the Clifford Materials Reactivity Testing system from its inception. Its background is found in various projects and environments in which I have worked, including activity from military research performed in uniform as a soldier-scientist during the Viet Nam war. Although I worked with Dr. Hal A. Huggins for approximately two years during the mid-1980's, our parting was quite bitter and acrimonious over various scientific and ethical differences.

2. Clifford Consulting & Research (CCR) is not now, nor has it ever been associated with Dr. Hal A. Huggins. CCR does not now, nor has it ever performed any testing invented or developed by Dr. Huggins. CCR does not now, nor has it ever followed any testing protocol or methodology developed by Dr. Huggins or used any interpretive value or system developed by Dr. Huggins.

3. Hearings and actions taken by regulatory agencies against Dr. Huggins have not brought charges or accusations against CCR, and CCR has not been named in any such actions as either a defendant or participant or affiliate. It will be noted that some attorneys have confused 'Clifford Materials Reactivity Testing' and the work at CCR with testing provided by Dr. Huggins and his various associates under the term 'Serum Compatibility Testing'. CCR was not a participant in any of these hearings and actions against Dr. Huggins, and was not called upon to offer any comment or rebuttal during the actions.

4. In subsequent legal settings, such as hearings against Dr. Terry Lee in Arizona, CCR was invited to testify and offer evidence showing that 'Clifford Materials Reactivity Testing' was not the same testing or system as 'Serum Compatibility Testing' offered through Dr. Huggins and his associates. Among other matters, Dr. Lee was accused of practicing below the standard of dentistry in Arizona when he ordered testing from CCR for his patients. After hearing the evidence and discussion of the two tests, and establishing that Dr. Lee used only the 'Clifford Materials Reactivity Testing' with his patients, the charges against Dr. Lee in this matter were dropped. Actions accusing several other dentists in other states on testing charges similar to those brought against Dr. Lee have been dropped following the introduction of evidence developed in

the Lee hearing.

5. In the matter of hearings against Dr. Scott R. McAdoo, CCR was not named as a defendant,

participant or affiliate. When CCR learned that Dr. McAdoo was being charged with some of the same matters that had arisen against Dr. Lee in Arizona, CCR offered to provide input and testimony in Dr. McAdoo's behalf. Our offer was declined as not needed. Dr. McAdoo felt he could describe testing adequately on his own. I regret that Dr. McAdoo was not technically adept in describing laboratory methods and operations. Attorneys at Dr. McAdoo's hearing used much of the same misinformation / inaccuracies that had been used against Dr. Huggins in earlier hearings as if it were established fact. CCR was not permitted to enter any testimony, comment or clarifications.

6. We note that the folks at www.quackwatch.org have been quick to seize upon the Huggins and McAdoo hearings and the misinformation / inaccuracies that attorneys introduced on those occasions. For whatever reasons or agenda Quackwatch might be following, the subsequent evidence and clarifications (such as in the Lee hearings) have been completely ignored. They continue to assert that Huggins and CCR are one and the same, and that 'Clifford Materials Reactivity Testing' and 'Serum Compatibility Testing' are interchangeable names. In legal settings subsequent to the Huggins case, the differences have clearly been demonstrated.

With this background, may I share the purpose and goal of our testing as well as the protocol and process which is employed in our lab. While we protect our database, formulary data and patient and client information, there is nothing super secretive about our facility, methods and protocols. With reasonable advance notice to insure that federally-mandated patient privacy and security requirements are met, we invite guests to visit and observe the lab during operational hours so that they can actually see 'what we really do'.

Clifford Materials Reactivity Testing (CMRT) is intended to serve as a broad screening mechanism to detect existing sensitivities in the patient for constituents which might be released from restorative materials. It does not prove current toxicity, pathology, contributing source, etiology or even physical presence of the constituent at the time of testing. CMRT is, in fact, performed using blood serum. Our target moieties are IgG and IgM antibodies resident in the serum. The testing system is based on immune detection using precipitin methods similar to those used in detecting reactions with various viral, bacterial, fungal and environmental toxins and their components. Irritants (antigens) which are toxic or noxious for the individual nature of the patient will stimulate an attempt by the body to defend against and / or neutralize the offending substance. Part of the defense process is the templating and production of antibody which is highly specific for the antigen. The relationship between the antigen and its antibody is often referred to as being like a lock and key. We make antibodies that normally respond only to the antigen that stimulated their production, and not to some other irritant.

If we can find a meaningful presence of antibody which specifically reacts with eugenol (as an example), we know that the patient has encountered eugenol and that the substance has been offensive to the individual patient's nature. The patient is systemically sensitized. How did the encounter / exposure happen? It might have been due to use of a zinc oxide / eugenol temporary cement by the dentist. It could just as easily have been due to the cloves in grandma's sweet pickles, or a variety of other sources where eugenol is found. The source of the offending exposure is not especially important. In dental considerations, if the patient didn't get along with

eugenol from whatever originating source, the dentist will not want to place a temporary cement containing eugenol in that patient to further escalate the challenge.

The methodologies for antibody detection are well established and documented. One of these is the precipitin reaction. The precipitin method looks for the development of a precipitate when approximately equal quantities of antibody (in serum) and antigen (challenge) come together under controlled conditions. Without getting unreasonably bogged down in the immunology, we must be certain that the precipitate is truly a formation of the lock and key (antibody and its specific antigen). It is well-known that blood proteins, including the immunoglobulins, can form a non-specific precipitation or agglutination by simply mixing the proteins with chemicals out in the air.

CCR has carefully gone through the process of insuring that we are getting a specific precipitation in our testing, and not a mass non-specific reaction between protein and chemicals. This can be done by taking a serum sample from a patient who happens to adversely react with several different metals. Let us say that the patient reacts with nickel, mercury and cadmium. We can add a cadmium challenge to the patient serum and produce the expected precipitate. The precipitate is centrifuged down and the supernatant fluid is separated off into a new reaction vessel. The supernatant fluid contains residual serum (including globulin) and un-reacted challenge. If additional cadmium challenge is added to the supernatant fluid, no further precipitate is formed. The precipitate from the first test vessel is analyzed and demonstrated to contain globulin and cadmium challenge. The supernatant fluid now has a nickel challenge added, and new precipitate forms. This second precipitate is centrifuged down and the supernatant fluid is separated off into a new reaction vessel. The second precipitate can be analyzed and shown to contain globulin and nickel. The second supernatant fluid can be shown to contain serum proteins, including globulin. If either additional nickel or cadmium challenge is added, no new precipitate forms. If the remaining supernatant fluid is now placed with a mercury challenge, additional precipitate forms. Upon separation by centrifuging, the newest precipitate can be shown to contain globulin and mercury challenge. If separated off, the last supernatant fluid can have cadmium, nickel or mercury challenge added, but no new precipitate is formed. It does still contain residual serum protein, including globulin.

The order of presentation of the cadmium, nickel and mercury challenges can be altered, but the results will still show that the respective precipitates contain principally the specific challenge and globulin. Adding any additional cadmium, nickel or mercury after the third trial does not induce any extra precipitate in the residual supernatant fluid. As a final test, the final supernatant fluid can be shown to contain some remaining serum protein (including globulin). If this last supernatant fluid is mixed with a chemical known to produce a non-specific precipitate or agglutinate, such as ammonium sulfate, it will then show some final precipitation which is essentially free of any of the metallic challenges. This exercise demonstrates that our system reacts with the target challenge specifically, and does not simply form a non-specific agglutinate / precipitate as some have claimed. While such non-specific reactions are possible and recognized, our methods, reagents and procedures are designed to take this into account and to insure that we are providing good immunology and specific determinations. Please note that if we were simply precipitating or agglutinating protein on a non-specific basis, we would expect

that it would all come down on the first precipitation, and that supernatant fluids would contain no further protein (including globulin).

It should be noted here that metals are not good antigens by themselves, but make great haptens when attached to various ligands or other carriers. The hapten is that portion of the irritant which leads to specific templating in the antigen processing cascade and the formation of the specific lock and key antibody. The metal hapten can be used by itself in the challenge role in testing; it reacts nicely with the antibody by itself. It does need a carrier to induce antibody formation. It is possible that some metals can interact with each other's antibody (ie., cadmium and beryllium). However, this cross-reactivity has important implications in-vivo and is a valuable observation.

Serum for the testing is normally obtained by collecting whole venous blood via venepuncture and permitting the blood to undergo its normal clotting process by standing in the collection tube for 20-30 minutes. Whether collected for the CMRT or serum chemistries or for other immunological studies, etc., this process is familiar to any clinical lab technician. Once the blood has properly clotted, it is centrifuged for a period of 5-10 minutes to facilitate separation of the serum from the formed/clotted elements of the blood.

Following centrifugation, the serum will be removed to a transport tube and prepared for shipment to the laboratory in accordance with appropriate established regulations and protocols used in the clinical lab industry. CCR provides appropriate shipping containers and materials for overnight shipping with carriers such as UPS and FedEx. Our shipping materials and procedures meet the requirements as published for UN3373 movement of clinical testing materials.

Preparation for immune precipitin testing requires that challenge materials (antigens) be placed in a soluble form at controlled concentration. It is important to note that the CMRT does not involve any direct challenge with completely formed restorative materials, whether solid or 'dissolved'. Intact restorative materials are seldom ever a problem for the patient. Rather, it is the dissociable / ionized constituents which are released during electrolysis, corrosion, out-gassing, off-loading and curing that will likely be the issue. By knowing what constituents and ingredients a product contains, what is expected to be released during preparation, placement and curing, and what is likely to come out as part of ongoing corrosion actions, we can prepare a proper immune challenge for various chemical groups and families of compounds. It is not 'Restorative X' that will be the challenge, but rather the acrylates, phenols, cadmium or nickel compounds and salts, etc., that the patient is troubled with. These can be prepared in the soluble form needed for the immune challenge test antigens.

Testing is performed in a micro-titer environment using a precision tray with test wells. The test antigen is introduced into the well, followed by a controlled quantity of patient serum. Development of any precipitate is photometrically monitored and measured. If a precipitate forms at or above a relevant clinical threshold, it suggests that the patient is systemically sensitized to that antigen. This formation is a qualitative determination. It does not have the ability to describe any quantified degree of sensitive within the patient. Rather, it is a yes / no determination. The patient is sensitive or is not sensitive. Higher quantities of antibody may suggest a current quality level of exposure; lesser quantities may suggest a poorly stimulating

antigen or a long duration of time since the patient has been exposed.

CCR has examined CMRT serum testing results for patients who have known diagnoses of toxicity and / or reactivity issues as shown by other testing and evaluation systems. I have carefully correlated levels of antibody presence as found in such patients with their known clinical issues. This has permitted the establishment of appropriate challenge concentrations and relevant clinical thresholds for antibody presence for various challenge substances. The CCR thresholds, which are usually set approximately 20% below the levels found in independently diagnosed patients, serve as the boundaries between reporting the patient as showing sensitization for the certain challenge or being reported as a negative test finding. The thresholds permit us to screen patients effectively without false alarms from low noise levels of antibody which are formed by the immune system but which seem to have little or no clinical importance.

Once a data-set of reactivity with the challenges has been obtained for the patient, we will then proceed to our computerized database of trade-name restorative products. Here, we have record of those individual components and constituents which are expected to be released in a bio-available form from each product. Using an earlier example of zinc oxide-eugenol cement, if we have found that the patient has shown reactivity with eugenol and that this cement can be expected to release some eugenol, we will report that trade-name product as 'not well suited' for this patient. It may be perfect and reported as 'suitable' for the next patient, but where possible, the current patient may need to be considered for an alternate product. In the event that there are no alternatives available, then the doctor and patient can decide whether or not the potential risk of using zinc oxide-eugenol is appropriate, and can be alerted to follow the patient's progress for onset of any untoward symptoms if the product is used.

It is valuable to note that testing is advisory; we do not determine which materials must be used for a patient. Even for a product which might show as 'not well suited' for a certain patient, it may still be possible to use the product. Nearly all sensitivity issues are threshold and body-burden based. If the patient has some headroom between their current body burden and their individual threshold where compensatory mechanisms can no longer cope with the challenge, they may be able to use the product and never know the difference. This is especially so where materials release constituents very slowly. Alternately, if body burden can be reduced through appropriate detox regimens, the needed headroom might be created. However, in most cases, it is wise to select alternate materials which show as 'suitable' for minimizing risk to the patient. Our objective in testing is to provide as many choices as possible for the doctor and the patient. We religiously refrain from endorsing, recommending or promoting any certain products or types of products. Currently (November 2009), we report on more than 9,600 trade-name products in 32 application categories for the dental panel, and on more than 3,200 trade-name products in 30 application categories for the orthopedic surgical panel. We have provided our testing for more than 49,000 patients. In that database of patients, we have not found a single product that is absolutely, positively suitable for any and every patient. We likewise have not found any products which are absolutely, positively contraindicated for every possible patient. It is also well to note that our laboratory is inspected and licensed under a joint program of state and federal governments as is any other interstate clinical laboratory. We are CLIA compliant and we have passed muster for our methods, procedures and testing. Some labs change their names

periodically and move their facilities when they have regulatory and licensing problems. CCR has been in business for more than 20 years, operating under the same name, and has moved one time within the same community to obtain larger quarters.

Now, with specific regard to the Quackwatch article, I offer the following comments:

A. I cannot defend statements made by Dr. Hal Huggins and his associates which are frankly inaccurate or false. Some of these are cited in the materials which you have sent to me, and I take no responsibility for them. Inference by Quackwatch that Huggins' pronouncements are equally attributable to Clifford are wholly inaccurate and should not be. I can and have defended our testing, including defense in the legal setting. I do not feel that a court room or judicial setting is the best place to discuss science and clinical testing. It is not, however, an impossible task. Our science and protocols have passed muster with both Colorado State and US Federal inspectors who have been on-sight at our lab. They have also been found acceptable by the International Academy of Oral Medicine and Toxicology as a preferred procedure, and I am invited as a lecturer to speak about our work and testing before various professional bodies.

B. Levy's testing lab and offerings have been synonymous with Huggins and have never been legitimately called Clifford Materials Reactivity Testing. Levy has never had any business or professional relationship with Clifford in any manner whatsoever. Clifford has never provided information, data or testing services for Levy.

C. The case and legal action against Dr. Scott McAdoo has been addressed on page 2 of this document. I have not had any contact with Dr. McAdoo since the legal action was taken and do not know how he and his legal counsel approached the matter of testing. I would have greatly appreciated the opportunity to assist in defending our work in his behalf.

The citation of the Huggins case finding in McAdoo's hearing that testing has no scientific basis and is without clinical justification has been presented as a determined and proven fact. It reality, it is a conclusion that came from an assistant Attorney General and was never challenged, countered or defended by Huggins and his attorney. The citation regarding allergy to a dental product needing to be referred to an allergist is not necessarily accurate. The allergist might bring very useful skills and observations to bear in severe cases, but most lesser cases are routinely handled by the dentist. In the ICD-9 diagnosis coding books, the codes for dental material allergy matters are in a segment of joint medical-dental usage.

Of more telling importance, the summary of the McAdoo case illustrates that those who made the summary determinations *DO NOT UNDERSTAND THE DIFFERENCE BETWEEN ALLERGY AND SYSTEMIC SENSITIVITY*. The CMRT does not now, nor has it ever been suggested for use in assessing allergy, diagnosing allergic reactions, the presence of IgE antibodies or any other pathology. It is a screening tool for systemic sensitivity at or above a relevant clinical threshold and is based in IgG and IgM antibodies. Repetition of the mis-concept by the Quackwatch writer implies the same lack of understanding.

D. In summarizing why serum-based testing is not valid, the Quackwatch writer repeats the erroneous statement that dental materials to be assessed are dissolved into a 'solution' and mixed with blood serum. This is simply false.

E. The writer states that the patient will need to undergo changing fillings with very expensive dental procedures using materials recommended by the testing. *CLIFFORD MATERIALS REACTIVITY TESTING has never recommended a material to anyone. Period.* The need for replacement of materials is an evaluation made by the dentist. Testing is an adjunct service to help the doctor avoid materials which may present a greater level of risk in the specific patient. Even if a product is showing as not well suited for the patient, if they are wearing it successfully, the doctor may determine that the patient is below threshold and elect not to place more of the same but does not necessarily remove any existing material.

F. As to the argument of non-specific agglutination of chemicals and serum protein out in the air, this certainly can happen. However, as explained on page 3 of this document, it does not happen in genuine immune reactions which take place by controlled-range equilibria and controlled environment between antigen and antibody (or hapten). I am left with the impression that the Quackwatch writer has not been near an immunology lab bench for quite a while and has forgotten much of what was taught to them in First-Year Immunology.

G. *The CMRT DOES NOT NOW, NOR HAS IT EVER, SHOWN COMPATIBILITY WITH ANYTHING.* It is a screening system designed to demonstrate *reactivity/sensitivity* with certain constituents which might be found in restorative products. When reactivity data have been developed at the testing bench, the data will be applied against a database of products. If a product contains and is expected to release a constituent for which reactivity has been seen in the patient, that restorative product is flagged sinply as 'Not Well Suited' for this specific patient. Any product in the database which has not shown any matches between its constituents and those which are reactive for the specific patient are flagged sinply as 'Suitable' and are among the safest for the doctor to choose from. *REDUCING RISK FOR THE PATIENT IS THE GOAL AND PURPOSE OF TESTING.* It identifies products for which the doctor may wish to choose a substitute. If a substitute is not available, at least the doctor and patient are alerted up front that the patient may need to have more frequent following to insure that a threshold is not acquired and the patient develops a clinical issue.

It would frankly be very useful if the Quackwatch crowd would simply call and ask to come and visit the operation at the lab. I'm not concerned about sitting down to answer their questions, nor do I have any grave concern about them seeing the wheels turn and the lights blink at our bench. I would even be happy if they would simply ask for a speaking schedule and send an anonymous representative to attend the meeting or conference to see what we actually teach and present. At least they might be able to differentiate Clifford Consulting & Research from Huggins and company if they did.

Parenthetically, it is interesting to visit Quackwatch to see whom they are 'writing' about. It reads like a Who's Who' of alternative and complementary medicine. When a full Professor of Medicine from an accredited U.S. medical school such as Dr. Andrew Weil at the University of

Arizona (as an example) becomes one of the 'quacks' because he heads up their Department of Alternative Medicine, you start to get the mood of the web site. Are these folks afraid of 'NEW' and 'CHANGE'?

It is also well to see what has taken place when some of the writers of the Quackwatch, such as Dr. Robert Baratz, are called as an expert witness in court. You begin to see the shallowness of both their research and their technical knowledge (in spite of numerous degrees). A court case against Tim Bollen is priceless in exposing Dr. Baratz for what he is after Dr. Baratz was called as an expert witness against Bollen. The expert testimony provided was so shallow, contradictory and confused that all charges against Bolen were summarily dismissed by the court.

Further, when debating Dr. Murray Vimy, DMD, a dentist and an Associate Professor of Medicine at the University Of Calgary, Dr. Baratz did not even understand the reading of a straightforward radiological scan presented by Dr. Vimy of a lab research animal which demonstrated the uptake of radio-labeled substances. A cloth embedded with material capable of releasing soft alpha irradiation was employed to help outline the body of the animal. The alpha irradiation is, of course, not sufficiently strong to penetrate the tissue of the animal, but provides a useful background shading to outline the perimeter of the body. Dr. Vimy had received the assistance of a team of nuclear medicine professionals from a world-class university facility in preparing his studies. Dr. Baratz pronounced the background shading produced by the alpha emitter components as being 'natural radiation' from the earth and then tried to claim that the entire radiograph was all just natural radiation and that the results of the study meant nothing. It truly makes you wonder who is minding the quacks at Quackwatch.