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How the "Urine Toxic Metals" Test Is Used to Defraud Patients

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Many patients are falsely told that their body has dangerously high levels of lead, mercury, or other heavy metals and should be "detoxified" to reduce these levels. This article explains how a urine test is used to defraud patients.

The report pictured to the right is a "urine toxic metals" test from Doctor's Data, a Chicago-based laboratory that performs tests for many chelation therapists and other offbeat practitioners. The patient who gave it to me was told by his doctor that his mercury and lead levels were high and should be reduced with EDTA chelation therapy.

The report classifies the man's lead and mercury levels as "elevated because they are twice as high

URINE TOXIC METALS							
		LAB#: [REDACTED] PATIENT: [REDACTED] SEX: Male AGE: [REDACTED]	<i>Patient copy</i>	CLIENT#: [REDACTED] DOCTOR: [REDACTED]			
POTENTIALLY TOXIC METALS							
METALS	RESULT µg/g CREAT	REFERENCE RANGE	WITHIN REFERENCE RANGE	ELEVATED	VERY ELEVATED		
Aluminum	< dl	< 25					
Antimony	0.3	< 0.6					
Arsenic	44	< 120					
Beryllium	< dl	< 0.5					
Bismuth	< dl	< 10					
Cadmium	0.5	< 2					
Lead	10	< 5					
Mercury	6.3	< 3					
Nickel	4.4	< 10					
Platinum	< dl	< 1					
Thallium	0.2	< 0.7					
Thorium	< dl	< 0.3					
Tin	9.5	< 9					
Tungsten	< dl	< 0.7					
Uranium	< dl	< 0.1					
CREATININE							
	RESULT mg/dL	REFERENCE RANGE	2SD LOW	1SD LOW	MEAN	1SD HIGH	2SD HIGH
Creatinine	46	45 - 225					
SPECIMEN DATA							
Comments: Date Collected: [REDACTED] Date Received: [REDACTED] Date Completed: [REDACTED]		Method: ICP-MS <dl: less than detection limit Provoking Agent: DMPS/EDTA		Collection Period: timed: 6 hours Volume: 1300 ml Provocation: POST			
Toxic metals are reported as µg/g creatinine to account for urine dilution variations. Reference ranges are representative of a healthy population under non-challenge or non-provoked conditions. No safe reference levels for toxic metals have been established.							
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as the upper limit of their "reference ranges." However, this classification is misleading because:

- The report states that the specimen was obtained after patient was given a "provoking agent," but the reference range is based on non-provoked tests.
- The levels, whether provoked or not, are not high enough to conclude that the patient has a problem that requires attention.
- Even if a problem exists, chelation may not be the best course of action.

Doctor's Data also processes the urine toxic metals test for The Great Plains Laboratory, Inc., of Lenexa, Kansas. Urine toxic metal testing is also performed in the United States by Genova Diagnostics (Asheville, North Carolina) and Metametrix Clinical Laboratory (Duluth, Georgia), which [Genova purchased in](#)

[2012.](#)

Why Provoked Testing Is a Scam

Mercury is found in the earth's crust and is ubiquitous in the environment. Because of this, it is common to find small amounts in people's urine. The body reaches a steady state in which tiny amounts are absorbed and excreted. Large-scale population studies have shown that the general population has urine-mercury levels below 10 micrograms/liter, with most people between zero and 5 [1]. Similarly, many people circulate trivial amounts of lead.

Urine lead and mercury levels can be artificially raised by administering a scavenger (chelating agent) such as DMPS or DMSA, which attaches to lead and mercury molecules in the blood and forces them to be excreted. In other words, some molecules that would normally recirculate within the body are bound and exit through the kidneys. As a result, their urine levels are artificially and temporarily raised. How much the levels are raised depends on how the test is administered. The standard way to measure urinary mercury and lead levels is by collecting a non-provoked urine sample over a 24-hour period. Because most of the extra excretion takes place within a few hours after the chelating agent is administered, using a shorter collection period will yield a higher concentration.

When testing is performed, the levels are expressed as micrograms of lead or mercury per grams of creatinine ($\mu\text{g/g}$) and compared to the laboratory's "reference range." Well-designed experiments have demonstrated how provocation artificially raises urinary output.

- One experiment involved ten healthy people whose urine was examined before and after receiving a 1-hour infusion of calcium disodium EDTA. The infusion increased the excretion of lead about 6 times over the baseline level [2].
- Another experiment tested workers who had industrial exposure to mercury. The researchers reported that provocation with DMSA raised the 24-hour average urine mercury level from 4.3 $\mu\text{g/g}$ before chelation to 7.8 $\mu\text{g/g}$ after chelation [3].

Both of these studies used a 24-hour urine collection period. Because most of the extra excretion occurs toward the beginning of the test, it is safe to assume that the provoked levels would have been much higher if a 6-hour collection period had been used.

Practitioners who use the urine toxic metals test typically tell patients that provocation is needed to discover "hidden body stores" of mercury or lead, which they also refer to as "body burden" or "mercury efflux disorder." However, the above experiment proved that provocation raises urine levels as much in exposed workers as in unexposed control subjects and that rise is temporary, should be expected, and is not evidence of "hidden stores." The scientific community does not recognize "mercury efflux disorder" as a diagnosis or even as a theoretical possibility.

The "hidden stores" notion was further debunked by a study that compared non-provoked and DMSA-provoked urine specimens from 15 children with autism and 4 normally developing children who ranged from 3 to 7 years old. After a baseline specimen from each child was collected, the DMSA was given in three doses over a 16-hour period, and the specimens were collected for 24 hours and tested for lead, mercury, arsenic, and cadmium. The testing was performed by the Mayo Clinic's laboratory, which used reference ranges of 80 $\mu\text{g/liter}$ as the upper limit of normal and over 400 $\mu\text{g/liter}$ for the lower limit of the potentially toxic range for lead and 10 $\mu\text{g/liter}$ as the upper limit of normal and over 50 $\mu\text{g/liter}$ for the lower limit of the potentially

toxic range for mercury. All of the normal children and 12 of the autistic children excreted no detectable amount of any of the tested materials. In one child, DMSA provocation raised the urine lead level from undetectable to 6 µg/liter, which the researchers said was far too low to be of concern. In another child, the mercury level rose from undetectable to 23 µg/liter, but after fish was removed from that child's diet for more than a month, it fell to 5. The study showed that when laboratory measurements are accurate and proper reference standards are used, neither autistic nor normal children are likely to have problematic levels of lead or mercury, even when provoked testing is used, but fish-eaters might consume enough mercury to enable provocation to produce an inflated value. The authors concluded that the proportion of autistic participants in this study whose DMSA-provoked excretion results demonstrated an excess chelatable body burden of arsenic, cadmium, lead or mercury was zero [4].

Neither Mayo Clinic, nor any other legitimate national laboratory, has reference ranges for "provoked" specimens. Further, the reference ranges for normal urine heavy metal levels used by Mayo Clinic and the largest national reference lab, Quest Diagnostics, are the same.

In contrast, Doctor's Data uses reference values of less than 3 ug/g for mercury and 5 ug/g for lead. Standard laboratories that process non-provoked samples use much higher reference ranges [4,5], which means that if all other things were equal, Doctor's Data is far more likely than standard labs to report "elevated" levels. But that's not all. A disclaimer at the bottom of the above lab report states—in boldfaced type!—that "**reference ranges are representative of a healthy population under non-challenge or nonprovoked conditions.**" In other words, they should not be applied to specimens that were obtained after provocation. Also note that the specimen was obtained over a 6-hour period, not the standard 24-hour period, which raised the reported level even higher.

The management at Doctor's Data knows that provoked testing artificially raises the urine levels and that the length of collection time greatly influences the results. David W. Quig, Ph.D., who is Doctor's Data's vice president for scientific support, communicates regularly with chelation practitioners about how to interpret the urine toxic metal test results and how to discuss them with patients. In 2002, Quig and two others presented a study of mercury levels in urine collected two hours after DMPS administration to 259 patients at a Nevada clinic. More than 75% of the patients tested at 21 µg or higher, and most of the rest fell between 3µg and 20 µg [6]. At these levels, nearly everyone's mercury level would be classified as "elevated" or "very elevated" on the test reports. In a 2006 naturopathic textbook chapter, Quig acknowledged that mercury levels "are higher in specimens collected from 90 minutes to 2 hours after DMPS infusion than with longer collection times, because the peak rate of mercury excretion occurs about 90 minutes after infusion of DMPS." [7] Quig's chapter also states:

- There are no well-established guidelines for the interpretation of the results of the DMPS challenge test.
- Conclusions about toxicity cannot be made from the DMPS test results alone. Consideration has to be given to the overall medical examination, medical and exposure history, and presenting symptoms.
- DMPS does not provide direct information as to the level of mercury present in the central nervous system.
- DMPS is not an FDA-approved drug.

In 2004, Irish researchers found that administering DMSA to healthy, symptom-free volunteers multiplied their urinary mercury levels an average of about six times, raising them to levels similar to those reported elsewhere among people who—based on provoked testing—had been diagnosed

with mercury toxicity. The researchers concluded: "The oral chelation test using DMSA may lead to misleading diagnostic advice regarding potential mercury toxicity." [8]

In 2005, the Autism Research Institute, which promotes a spectrum of questionable autism treatments, issued a 42-page consensus position paper called *Treatment Options for Mercury/Metal Toxicity in Autism and Related Developmental Disabilities* [9]. Referring to provoked testing of urine specimens, the document states that "the reference range for the urine or stool generally involves a comparison to people who are NOT taking a detoxification agent, so that even a normal person would tend to have a high result." Quig is identified as one of 33 people who reviewed and endorsed the position statement.

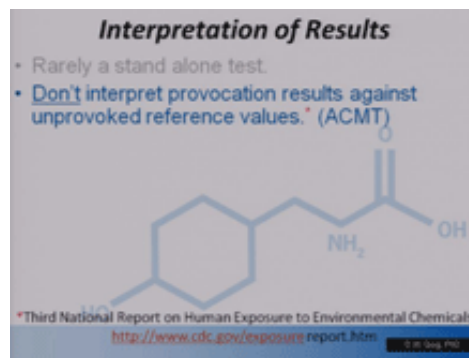
Despite all of this, Doctor's Data's reports classify mercury values in the range of 5-10 $\mu\text{g/g}$ as "elevated" and further state that "no safe reference levels for toxic metals have been established." Practitioners typically receive two copies of the report, one for the practitioner and one to give to the patient. Very few patients understand what the numbers mean. They simply see "elevated" lead or mercury, and interpret the "no safe levels" disclaimer to mean that any number above zero is a problem. (The fact that the reports use the familiar green, red, yellow and red colors of traffic lights may also have an effect.) The patient is then advised to undergo "detoxification" with chelation therapy, other intravenous treatments, dietary supplements, or whatever else the practitioner happens to sell.

This advice is very, very, very wrong. No diagnosis of lead or mercury toxicity should be made unless the patient has symptoms of heavy metal poisoning as well as a much higher nonprovoked blood level. And even if the level is in the 30s—as might occur in an unsafe workplace or by eating lead-containing paint—all that is usually needed is to remove further exposure. Chelation therapy is rarely necessary.

Warnings to Chelationists

Both Quig and attorney Algis Augustine (one of Doctor's Data's lawyer) caution chelationists not to rely solely on provoked urine testing to diagnose heavy metal toxicity. In April 2010, both spoke during the "Heavy Metals Detoxification Workshop" sponsored by the American College of Advancement in Medicine (ACAM), the leading organization that promotes chelation therapy. Quig's talk was titled "Appropriate Laboratory Testing for Metal Toxicology," during which he stated:

Rarely is it a stand-alone test, and **you absolutely should not interpret your provocation results against an unprovoked reference range.** . . . Consider the results in context with the amounts of all metals. Remember the synergy, physical exam, history of known exposure, symptoms, and other biomarkers. Very importantly, don't conclude metal toxicity based upon higher than average net retention. . . . Current standards of care define toxicity by blood level. So keep yourself off the radar, and don't be running around talking about "My patient has toxicity." No, they have they have significant retention of

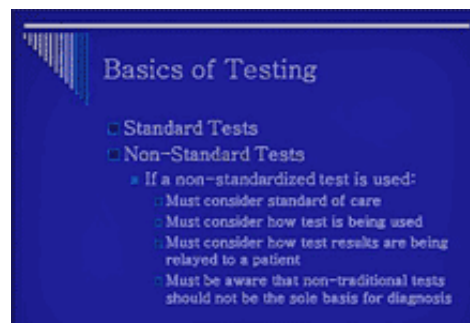


Slide from Quig's talk

metals that elicits toxic effects. OK? . . . Really be careful about using the word "toxicity" when we are talking about subclinical, chronic toxicity [10].

Augustine's talk, called "Legal Update," focused on how doctors can avoid trouble with their state licensing boards. After referring to the provoked urine testing as "nonstandard," he said:

I have a simple rule that I tell people all the time on nonstandard tests. Well, two simple rules. Number one: Don't give every patient the same nonstandard tests—all the time—because it makes it look like you're not thinking. . . . And number 2, and this is the most important thing: **Don't base your diagnosis, pure and simple, on a nonstandard test** [11].



Slide from Augustine's talk

Inappropriate Diagnosis and Treatment

Chelation therapy is a series of intravenous infusions containing a chelating agent and various other substances. One form of chelation therapy is occasionally used to treat lead poisoning. However, lead poisoning is rare and has well-established diagnostic criteria. Slight elevations of lead levels are not poisoning and need no treatment because the body will lower them when exposure is stopped. Proper diagnosis of lead poisoning requires symptoms of lead poisoning, not just a slightly elevated level. Acute poisoning is always accompanied by a rise in zinc protoporphyrin (ZPP), without which it should not be diagnosed. Chronic poisoning would have severe symptoms that would be obvious to anyone in addition to severely elevated lead (and ZPP) levels.

Doctors who offer chelation therapy as part of their everyday practice typically claim that it is effective against autism, heart disease and many other conditions for which it has no proven effectiveness or plausible rationale [12]. One such case was described in a 2009 decision by the U.S. Court of Federal Claims which found no credible evidence that childhood vaccinations cause autism. In that case, Colton Snyder underwent chelation therapy after a Doctor's Data urine test report classified his urine mercury level as "very elevated." After noting that the urine sample had been provoked (with DMSA) and that provocation artificially increases excretion, the Special Master concluded that a non-provoked test would have placed the result in the normal range. He also noted:

The medical records, including reports from Mrs. Snyder, reflected that Colten did poorly after every round of chelation therapy. . . . The more disturbing question is why chelation was performed at all, in view of the normal levels of mercury found in the hair, blood, and urine, its apparent lack of efficacy in treating Colten's symptoms, and the adverse side effects it apparently caused [13].

In March 2010, in a related case, another Special Master concluded that it made no sense to

compare the child's *post-provocation* urine test result to a reference range that is based upon *non-provoked* urine testing. [14].

In March 2009, Arthur Allen tried to interview an official at Doctor's Data but received no response to his request. However, he did manage to talk with someone at the company who said that the lab was doing about 100,000 of the tests per year. When he asked about the reference range problem, he was told there was no way to establish a reference range for provoked specimens, because provocation might be done with various chelating agents, at varying doses. "The tests are ordered by physicians, so they can interpret the results," the employee said. "They do what they want with this information." [15]

Despite provocation, the toxic urine test report sometimes shows no elevated levels. But that doesn't deter the doctors who are intent on chelating children. They simply tell parents that the children have trouble excreting heavy metals and the test may not detect "hidden stores." In other words, no matter what the test shows, they still recommend chelation.

In 1999, the Human Biomonitoring Commission of Germany's federal environmental agency stated:

The mobilization test with DMPS to assess an amalgam-related lead burden does not provide significant insight into the determination of spontaneously urine-excreted mercury within 24 hours. No validity can be assigned to such a mobilization test. . . . Furthermore, there do not exist any reference values for the stimulated mercury excretion in urine, and also no scientifically validated data beyond which health concerns exist; therefore, therapeutic consequences can not be deduced from the data of DMPS mobilization tests [16].

In 2003 and 2004, the New Jersey Department of Health and Senior Services and the U.S. Agency for Toxic Substances and Disease Registry investigated a case in which a 5-year-old child was undergoing chelation therapy for "metals exposure" that was diagnosed with provoked urine testing. The investigators identified no significant source of mercury contamination and noted that provoked testing was not an appropriate diagnostic test [17].

In 2004, CIGNA HealthCare Medicare Administration, which processes Medicare claims for Idaho, North Carolina, and Tennessee, issued a "Progressive Correction Action Review" which concluded that many claim submissions for chelation therapy had been inappropriate. This conclusion was documented by a study of 40 claims which found that in many cases, "heavy metal toxicity" was inappropriately diagnosed and no need for chelation with edetate calcium disodium was documented. The review criticized provoked testing and noted that it does not provide a basis for diagnosing past or current poisoning [18].

Aetna considers laboratory testing for heavy metal poisoning "medically necessary" for people with specific signs of heavy metal toxicity and/or a history of likely exposure—but "medically unnecessary" for people with only vague, ill-defined symptoms and no history of likely medical exposure. Its Clinical Policy Bulletin on chelation therapy also criticizes provoked testing [19].

In 2005, an ATSDR scientist reported:

Each year, ATSDR receives dozens of calls from individuals who have been chelated (challenged) with DMPS or DMSA prior to collection of any urine samples, and subsequently been diagnosed as having mercury poisoning. The sole basis of these

diagnoses was laboratory reports that indicated that the individual had been determined to have toxic levels of mercury, based solely upon comparison of post-chelation mercury values with historical (typically pre-chelation) values. Without exception these individuals have been advised to undergo additional chelation.

Some physicians have also looked to mercury as a possible cause of undiagnosed health problems and subsequent chelation therapy as a treatment for those problems. As a result, the use of chelation has expanded in recent years to include the treatment of mildly symptomatic or asymptomatic patients with no documented history of mercury exposure, and it is becoming increasingly, and unfortunately, common for practitioners to make a diagnosis of mercury intoxication and begin treatment without carrying out an adequate clinical workup [20].

In 2006, a National Institute for Occupational Safety and Health (NIOSH) health hazard evaluation team reviewed the records of two Broward County park employees who had been diagnosed with arsenic poisoning based on provoked urine tests. After concluding that no poisoning had taken place, the investigators noted that "Provoked urinary testing has resulted in many patients being falsely diagnosed with arsenic poisoning because the test measured the arsenic content of the diet." [21].

In 2007, the Oregon Lead Poisoning Prevention Program advised against the use of urine testing for diagnosing lead poisoning and also said that provoked testing should not be used for diagnostic purposes [22].

In 2009, the American College of Medical Toxicology (ACMT) issued a position statement which concluded that provoked testing "has not been scientifically validated, has no demonstrated benefit, and may be harmful when applied in the assessment and treatment of patients in whom there is concern for metal poisoning." [23]

In 2009, NIOSH investigators evaluated a suspected outbreak of antimony toxicity among fire fighters in Boca Raton, Florida who had been wearing fire-retardant pants that contained various chemicals. The investigation was triggered by hair analysis and urine toxic metal tests that had been ordered by a chelationist (Leonard Haines, M.D.) and performed by a commercial laboratory (Doctor's Data). Doctor's Data's reports alleged that all 30 of the fire fighters who had undergone hair analysis had antimony levels much higher than the "reference range" and that 23 who also had urine toxic metal testing showed "high" mercury levels. After a thorough evaluation found no real evidence of toxicity, the investigators advised:

The decision to perform laboratory testing for heavy metals, including antimony and mercury, should be based on whether or not documented health symptoms are consistent with overexposure to these metals. It is important to use reliable and recommended testing methods with well-validated reference ranges to measure the concentration of heavy metals in the body. Because results from elemental hair analysis and post-chelation-challenge urine tests do not provide sufficient evidence of heavy metal toxicity, they should not be used to justify searching the workplace for exposures or to treat heavy metal toxicity. In particular, they should not be used to justify chelation therapy, which can be potentially harmful to a patient [24].

The Online Petition

Many parents have expressed concern about the way that Doctor's Data reports its findings.

Several years ago, [a petition was posted to petitiononline.com](http://petitiononline.com) to ask Doctor's Data to stop comparing provoked tests results to non-provoked standards. By February 2006, there were 92 signers. The petition states:

To: To get matching reference ranges to people tested
To the CEO of Doctors data Inc.

We thank you for providing the extensive testing for toxic metals , fecal stools & all the other tests that us parents of children with autism and other disabilities have done at DDI.

However we would like to ask you to please use matching reference ranges to the people tested as it is impossible to get an accurate picture when the reference ranges do not match.

Eg. Urine toxic metals challenge test compares a childs urine sample AFTER provocation with DMSA to an UNPROVOKED reference range population of adults & kids. It is only natural that our kids will show results that are higher than the reference range.

Had the reference range population also been provoked, their results would have most probably been higher, which means our childrens results may not really be that high, it just appears that way.

The present tests compare apples to bananas.... provoked to unprovoked...we'd like to compare apples to apples please.

We the undersigned urge you to please seriously consider this petition and to give us matching reference ranges to the children tested as we need accurate test results in order to be able to do the correct treatments to get them better.

Sincerely,

The Undersigned

Regulatory Actions and Civil Suits

At least ten state licensing boards have taken action against doctors who used provoked urine testing as a prelude to chelation. In some of these cases, the test was of major importance in the public documents that describe the board actions. In the rest, the board action emphasized other misconduct and the test was either briefly mentioned or I learned of its relevance through other means. There have also been four civil suits against Doctor's Data and doctors who used them that alleged fraud.

- In 2002, the Medical Board of California charged Ilona Abraham, M.D. with unprofessional conduct, incompetence, gross and repeated negligence, and inadequate recordkeeping in connection with her management two patients. In both cases, Abraham had failed to perform an adequate history and physical examination and had administered chelation therapy after diagnosing heavy metal toxicity based on provoked testing. In 2004, the case was settled by a consent agreement and order under which Abraham agreed to serve three

years probation, during which time she would (a) pay about \$26,000 for costs, (b) take certain remedial courses, and (c) engage the services of a practice monitor [25].

- Connecticut has included a provoked testing ban in settlement agreements with two practitioners. In 2005, Robban Sica, M.D., signed a consent order under which she was prohibited from using a provoked test to diagnose heavy metal toxicity [26]. In 2006, George Zabrecky, D.C., was ordered to stop all testing that might be preliminary to chelation therapy [27].
- In 2006, Washington's Bureau of Medical Quality Assurance charged Stephen L. Smith, M.D., with unprofessional conduct for relying on unreliable tests that included a urine toxic metals test. In 2007, he was ordered to pay a \$5,000 fine and undergo a practice evaluation [28].
- In 2007, Tennessee suspended the license of Joseph E. Rich, M.D., after concluding that he had mismanaged the care of 15 patients, including three who were chelated after undergoing a provoked urine test. [29].
- In 2007, the Texas Medical Board charged William Rea, M.D. with (a) using pseudoscientific test methods, (b) failing to make accurate diagnoses, (c) providing "nonsensical" treatments, and (d) failing to properly inform patients that his approach is unproven. A urine toxic metals test was used in two of the five cases involved. The complaint was settled in 2010 with an agreed mediated order under which Rea is must inform patients that his therapies are disputed and that certain injections he uses contain no detectable amounts of their "active" ingredients. As part of the settlement, the charges not related to informed consent were dropped [30].
- In 2007, the California Medical Board revoked the license of Alan Schwartz, M.D., as a result of several types of misconduct, including unsubstantiated diagnoses and unwarranted treatment of four children [31].
- In 2007, the North Carolina Medical Board charged Rashid A. Buttar, D.O., with exploiting four patients by charging exorbitant fees for worthless tests and treatments. At a 2008 hearing, Buttar indicated that he recommends chelation for nearly all patients who consult him and routinely uses the urine toxic metals testing to evaluate them. In 2009, the charges were reasserted and four more cases were added [32,33]. Rather than getting into a lengthy and complicated legal battle, the case was settled with a consent agreement under which Buttar agreed to be reprimanded for treating an out-of-state autistic child whom he had never examined and the board dropped all other pending charges [34].
- In 2007, the Pennsylvania Board of Medicine temporarily suspended the license of Roy Kerry, M.D. following the death of a 5-year-old autistic child to whom he administered chelation therapy [35]. In 2009, Kerry signed a consent order under which he was suspended for six more months, to be followed by 2 1/2 years of probation. He was also barred from chelating children under age 18 in the future [36]. Kerry was also sued by the victim's parents [37]. The suit was settled in 2010 with payment of an undisclosed sum.
- In 2008, Rick Pfister filed a class action suit charging that he was improperly given chelation therapy after being improperly diagnosed with a urine toxic metals test. The complaint states that his urine was tested after he received an injection of DMPS and alleges that the test report was "negligent or fraudulent" because it compared his results to unprovoked sample ranges. The defendants were Doctor's Data, the Medical Wellness Institute, and the doctor who administered the test [38]. In 2012, the judge dismissed Doctor's Data after concluding that (a) the argument that Doctor's Data used an inappropriate reference range was not legally sufficient to conclude that it made a "knowing misrepresentation of fact as required to support a claim of actual fraud, and (b) negligence cannot be established because Pfister's doctor was responsible for interpreting the test [39,40].

- In 2008, the Texas Medical Board began investigating Jesus Caquias, M.D., medical director of the CARE Clinics, a facility in Austin, Texas that specialized in treating autistic children and routinely used the urine toxic metals test to persuade parents to have their children chelated [41]. In 2009, several months after the clinic owner announced that insurance companies had demanded records to back up her insurance claims, the clinic was raided by the FBI and closed [42].
- In 2009, 43-year-old Ronald Stemp sued Caquias, CARE Clinics, the clinic's owner, and Doctor's Data for fraud, negligence, and conspiracy. The suit petition states that Stemp originally sought help for memory loss, inability to sleep, difficulty concentrating, and depression. After taking a urine toxic metals test and several other tests, he was falsely diagnosed with heavy metal poisoning and advised to undergo intravenous chelation therapy. Stemp's insurance company was reportedly billed for a total of \$180,000 [43].
- In March 2010, the Texas Medical Board filed charges against Caquias that dealt with three patients seen at CARE's Austin clinic and one seen at the CARE's Tampa clinic. In 2011, the complaint was amended to add the Stemp case [44]. In 2012, the charges were dismissed for a very unusual reason. The board's complaint centered around the question of whether or not Caquias kept adequate records and did not address whether Caquias's approach reflected poor medical judgment. However, some records became available because the records in FBI custody were destroyed after a pilot intentionally crashed his plane into the FBI building in Austin. After Caquias testified that the missing records would have justified his patient management, the administrative law judges concluded that without complete records, the board could not prove its case [45] and the complaint was dismissed [46].
- In November 2009, Ardis Morschadt, in a suit against several practitioners and a clinic in California, charged Doctor's Data with negligence, intentional misrepresentation, and conspiracy to commit fraud because its test report compared a provoked test result with a nonprovoked standard [47].
- In February 2010, Vincy Tidwell, Jr, a former patient, charged Dr. Buttar with violating North Carolina's Unfair and Deceptive Trade Practices Act by fraudulently representing that "detoxification" would cure Tidwell's prostate cancer [48]. I believe Tidwell had a good case, but his lawyers withdrew it because they thought that Buttar had no seizable assets.
- In February 2010, in a suit against naturopath Mathew Schlechten, a Montana jury awarded \$501,007.68 to the widow of John Sisson, who died of a heart attack at age 52 [49]. Testimony in the case indicated that although Schlechten knew that Sisson had anginal pain, he failed to refer him for medical evaluation. Instead he administered chelation therapy after using a provoked urine test to persuade Sisson that he was toxic.
- In March 2010, James Coman filed suit on behalf of his 7-year-old son against Anju Usman, M.D., Daniel Rossignol, M.D., and Doctor's Data. Among other things, the complaint indicated that—based on the results of provoked urine testing—the boy was inappropriately treated for nonexistent metal toxicity for more than four years [50]. In 2014, the suit was voluntarily withdrawn, but this type of withdrawal preserves the right to file it again until the boy reaches 19 years of age.
- In May 2010, the Texas Medical Board charged "autism specialist" Seshagiri Rao, M.D. with nontherapeutic prescribing, failure to secure informed consent, and fraudulent billing related to his mismanagement of five children with autism or autism spectrum disorder. The complaint states that Rao used an inappropriate urine test to diagnose nonexistent "heavy metal toxicity," inappropriately treated the patients with chelation therapy, and pretended to insurance companies that he was treating heavy metal toxicity rather than autism [51].
- In May 2011, the Georgia Composite Medical Board concluded that Viktor R. Bouquette, M.D. had improperly diagnosed and treated Susan Alexander, a 56-year-old woman who died in 2002 while undergoing intravenous chelation therapy. The diagnosis was based on a

provoked urine test. The consent order requires Bouquette to (a) pay a \$5,000 fine plus \$800 for board costs, (b) complete 20 hours of continuing medical education in environmental medicine and 10 hours in record-keeping, and (c) refrain from providing intravenous chelation therapy to patients without fully documenting the need for such treatment on the patient's chart [52]. In 2003, the patient's survivors sued Bouquette, several other staff members at the clinic where he worked, and Metamatrix, which had tested the provoked urine specimen. In 2006, Metamatrix settled in an agreement with confidential terms. The suit against Bouquette and the others was dropped.

- In October 2011, the Illinois Department of Financial and Professional Regulation charged Usman with unprofessional conduct in her management of the Coman boy. The complaint stated that she failed to obtain informed consent for his treatment, failed to maintain appropriate medical records, and prescribed chelation therapy, dietary supplements, hormones, enzymes, antifungal drugs, and various other treatments that have not been proven effective against autism. The complaint also noted that provoked urine testing does not provide a basis for the diagnosis of heavy metal toxicity [53]. In 2012, Usman was charged with unprofessional conduct in connection with her management of another child [54]. Both complaints were settled in 2014 with a consent agreement under which Usman—without admitting or denying fault—was fined \$10,000, placed on indefinite probation for a minimum of one year, and ordered to submit 10 charts quarterly to another physician for review [55].
- In April 2012, the British Medical Council Fitness to Practice Panel concluded that (a) Dr. Jean Monro had improperly administered chelation therapy after improperly diagnosing lead toxicity with a provoked urine test (performed by Doctor's Data) and that the test alone "has no demonstrated benefit in the diagnosis of lead toxicity." The case was concluded with a formal warning that barred Monro from doing provoked testing or chelation therapy [56]. In July 2012, I noticed that Doctor's Data Web site contains a testimonial from Monro stating that Doctor's Data's "stool tests and investigations for heavy metals through urine tests have been the mainstays of our management of patients." [57]
- In April 2012, the Oregon Medical Board charged Christopher Hatlestad, M.D., with administering chelation therapy to five patients after they were improperly diagnosed with lead and/or mercury toxicity. In each case, the diagnosis was based on provoked testing. In December 2012, Hatlestad signed a stipulated order that reprimanded him, placed him on probation for five years, and prohibits him from (a) using or approving provoked testing, (b) treating or authorizing treatment for heavy metal toxicity, or administering or authorizing any form of chelation therapy [58].
- In 2013, the Oregon Medical Board declared that provoked testing "does not meet the standard of care for diagnosis of heavy metal toxicity." [59]
- On June 2014, Washington's Medical Quality Assurance Commission charged Stephen L. Smith, M.D., with unprofessional conduct in a case similar to the one for which he was disciplined in 2007. The statement of charges noted that he had diagnosed an autistic adolescent with "toxic encephalopathy or lead poisoning" despite the fact that (a) there was no evidence to support this diagnosis, the patient had no signs of lead poisoning and no history of exposure to lead, and (c) the patient's lead levels were in the normal range [60]. The case was settled with a consent agreement in which he stipulated that the charges were fact based and the board ordered him to (a) pay a \$1,000 fine, (b) stop treating patients under the age of 18, and (c) stop doing provoked testing. He must also refrain from treating adults who are not also under the care of a primary-care provider or a physician who is board-certified in a subspecialty of internal medicine [61].
- In 2015, the Oregon Medical Board disciplined Richard C. Heitsch, M.D., for chelating six patients unnecessarily. In five of the six cases, Heitsch used provoked testing to diagnose

nonexistent metal toxicity. The board reprimanded him, fined him \$10,000, and ordered him to stop treating heavy metal toxicity or administering chelation therapy [62].

- In 2015, the Minnesota Department of Health issued a fact sheet which stated that (a) heavy metal toxicity does not normally occur in the absence of extraordinary exposure, (2) chelation is almost never a first-line treatment and is known to be of no value in many cases, (c) nonspecific "screening" is of no value, (d) testing in response to nonspecific symptoms or in the absence of suspected exposure is of no value, and (e) "the results of provoked urine studies have no role in determining the body's burden of toxic metals, nor the need for chelation therapy." [63]

The Regulatory Gap

The laboratories that perform urine toxic metals tests are certified by CLIA, the federal agency that certifies laboratories. CLIA examines how tests are performed, but it does not consider how their results are interpreted. Widely used diagnostic tests require FDA clearance or approval, but the agency has not attempted to regulate tests that are used only by the laboratories that develop them. During the past few years, however, the FDA has become concerned about laboratory-developed tests (LDTs) that are used to guide treatment decisions [64]. In 2014, the FDA notified Congress that it had drafted a regulatory framework that includes pre-market review. In November 2015, it reported on twenty LDTs, noting that some of them can cause patients to undergo unnecessary treatments and potentially delay diagnosis of their true condition [65]. The report classified provoked testing for heavy metals as "a test linked to treatments based on disproven scientific concepts" and noted:

- In clinical use, patients with positive urine chelation challenge tests may not have heavy metal toxicity.
- False-positive results may lead to the administration of inappropriate, unproven, or dangerous therapies [65].

The Bottom Line

The urine toxic metals test described above—whether provoked or not—is used to persuade patients they are toxic when they are not. I believe that several agencies can and should do something to stop this deception.

- The FDA can and should ban laboratory-developed tests that provide clinically meaningless results. As part of this process, it should evaluate any software that generates interpretations.
- State licensing boards could prohibit the use of provoked testing and discipline practitioners who use it.
- State laboratory licensing agencies could prohibit testing of provoked specimens or order Doctor's Data to raise its reference ranges and to stop comparing provoked test results to these non-provoked ranges.
- The Centers for Medicare & Medicaid Services' Division of Laboratory Services can also ban the testing of provoked specimens.
- State attorneys general can seek injunctions based on violations of consumer protection laws.
- In addition, all of these agencies can and should issue public warnings.

People who have been victimized can also strike back. Practitioners who prescribe or administer chelation based on a urine toxic metal test report can be sued for malpractice, fraud, and battery,

and might even be liable for violating their state Unfair Trade Practices Act, which can result in an award of triple damages. [Consumers can also complain to the Better Business Bureau about the test.](#)

I recommend avoiding any practitioner who uses the urine toxic metals test as described above. If provoked testing has been used to trick you, [please send me an e-mail describing what happened](#) and include your phone number and, if possible, a scanned copy of the test report.

Doctor's Data does not like this report. After I refused to their demand to remove it, they sued me. To read about the suit, [click here](#).

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