

**Wisconsin State Laboratory of Hygiene
Board of Directors Meeting
April 21st, 2015
1:00 P.M – 4:00 P.M.
2601 Agriculture Drive
Madison, WI 53718**

**APPROVED MINUTES
February 10th, 2015**

MEMBERS PRESENT: Dr. Robert Corliss (Vice-Chair), Jeffery Kindrai, Charles Warzecha (on behalf of Karen McKeown), Darrell Bazzell, James Morrison, Jack Sullivan, Carrie Lewis, Dr. Charles Brokopp

WSLH STAFF PRESENT: Dr. Peter Shult, Dr. David Warshauer, Dr. Daniel Kurtycz, David Webb, Cynda DeMontigny, Marie Ruetten, Steve Marshall, Steve Strebel, Kristine Hansbery, Amy Miles, Michele Smith, Erin McCarthy and Nathaniel Javid

DNR STAFF PRESENT: Steve Geis, Ron Arneson

GUESTS PRESENT: Darren Berger, Dave Guberud, Rebecca Moritz

Vice-Chair Dr. Robert Corliss called the meeting to order at 1:00 P.M. in Chair Barry Irmen's absence.

Item 1. UPDATE ON BOARD MEMBERSHIP

Dr. Brokopp introduced Michelle Wachter, the new representative from the Department of Agriculture Trade and Consumer Protection (DATCP). Ms. Wachter is the Division Administrator for the Division of Management Services at DATCP with 33 years of state service, including 28 years in management. Dr. Brokopp had the Board introduce themselves to Ms. Wachter. Dr. Brokopp also recognized two former board members who have since resigned. Susan Buroker (DATCP) retired early January 2015 and Dr. Ruth Etzel (UW-Milwaukee Zilber School of Public Health) accepted a position with the Environmental Protection Agency and has moved from Wisconsin. Dr. Brokopp asked the Board to adopt a motion to recognize the service of Ms. Buroker and Dr. Etzel. Jack Sullivan approved the motion seconded by Dr. Robert Corliss.

Item 2. APPROVAL OF MINUTES

Approve the minutes of the November 4, 2014 board meeting as submitted. Jeffery Kindrai made a motion to approve, seconded by Carrie Lewis. Jack Sullivan abstained. The motion passed on a unanimous vote.

Item 3. REORGANIZATION OF AGENDA

There was no reorganization of the agenda.

Item 4. PUBLIC APPEARANCES

There were no public appearances.

Item 5. BOARD MEMBERS' MATTERS

Dr. Brokopp asked Board members from state agencies to comment on the Governor's recent budget proposal and the impact on their respective agency. Jack Sullivan (DNR) mentioned that position reductions and reduction targets, among others will be implemented to manage the challenge we have been given. Chuck Warzecha (DHS) and Michelle Wachter (DATCP) echoed that they will be preparing with position reductions and reduction targets along with determining what the next steps will be.

Item 6. ELECTION OF OFFICERS

Jack Sullivan made a motion to nominate Dr. Robert Corliss for the position of Chair and Jeffrey Kindrai for the position of Vice-Chair, and Dr. Charles Brokopp for Secretary for the 2015-16 term. Chuck Warzecha seconded the motion and Jeffery Kindrai and Dr. Robert Corliss abstained. The motion passed unanimously.

Item 7. SCIENTIFIC PRESENTATIONS

Dr. Daniel Kurtycz, Medical Director, WSLH introduced the scientific presentations from the WSLH Disease Prevention Division. Dr. Kurtycz provided the Bethesda System 2014 update. The Bethesda System for cervical cytology is the reporting system that most of the world uses for the diagnosis and reporting of Pap test results. It was begun in 1988 to simplify reporting and to establish uniformity. Dr. Stanley Inhorn (WSLH Laboratory Director 1966-1980) was very involved in the initial effort and more recently, Dr. Ritu Nayar of Northwestern University and Dr. David Wilbur of Harvard University initiated the first revision of the system in over a decade. Since the federal budget sequestration, the NIH has not had funding to support conferences, website and infrastructure for these types of efforts. In response, the American Society of Cytopathology stepped in to update the system for reporting. The ASC held the needed

conferences and provided the office support. Dr. Kurtycz was asked by Drs. Nayar and Wilbur to write one of the chapters and manage the images for the new book. The University of Wisconsin provided logistical support for a significant portion of the electronic communications surrounding the project. The chapter written by Dr. Kurtycz is one of the longest and describes the basic cellular morphology central to cytologic analysis in addition to various inflammatory, reactive and infectious conditions.

Dr. Kurtycz mentioned that a website update will also be updated following this publication. There will be many more images than on the previous site, incorporating modern microscopy while maintaining some original examples. Search capabilities will be maintained and enhanced. The website will hopefully go live in the next several months. A new section on virtual microscopy will be added to the website. Although we do not plan to put virtual images on the initial revised website, we will generate a slide set of major entities within the next year. Plans are in the works to make an iPad version as an adjunct to the printer version of the book.

Dr. Kurtycz introduced Erin McCarthy, WSLH Section Supervisor in Cytology. This year she was engaged in an effort studying human papillomavirus (HPV) in our population. She received a presentation award for her efforts. Ms. McCarthy presented on "Molecular Testing and Cervical Screening: Will One Test Fit All?" The current guidelines for cervical cancer screening recommend either a Pap test on its own, or a combination of Pap and HPV tests to determine the presence or risk of developing cervical cancer. Screening intervals range from 1-5 years, depending on individual history or risk. The Pap test has been around for over 70 years and is the tried and true method for diagnosing cancerous and pre-cancerous lesions of the cervix. The HPV test is a newer molecular-based test that detects a presence of the virus that is the precursor to cervical lesions. The presence of HPV does not necessarily mean a patient has a lesion, but persistent and multiple infections can eventually lead to their development.

In April of last year, the FDA approved the first molecular HPV test that can be used for primary screening, rather than a traditional Pap test. The approved testing platform is the Cobas HPV test from Roche Diagnostics, which we use in our lab. The method offers detection of fourteen high risk HPV types, as well as genotyping for the two most common types that cause cervical cancer. Ms. McCarthy presented a chart with the most common types of HPV that are associated with cervical cancer. There are over forty types and sixteen are considered to be high risk for cervical cancer. HPV 16 and 18 cause about 70% of cervical cancers in the general American population. Because of their high prevalence and risks, 16 and 18 have been the main focus of research, vaccination efforts, and current screening guidelines. They are the two types that can be genotyped by the Cobas HPV testing as a primary screening tool.

The WSLH cytology lab started using the Cobas HPV test in conjunction with Pap testing in July 2013. A large number of their pap tests with high grade, or pre-cancerous lesions were not positive for either HPV 16 or 18. Instead, the majority were either other high risk types or negative for HPV all-together. From July 2013 through September

2014, we had a total of 365 high grade Pap tests, and 168 of those had concurrent HPV tests and genotyping. Ms. McCarthy presented a chart that summarized the results of the HPV tests. Only about 44% were positive for HPV 16 or 18, 43% had one or more of the other high risk types, and 13% were negative for HPV all-together. This was surprising because national trends suggest we should be seeing closer to 70% with types 16 and 18.

These unexpected HPV results, it brought up the question “how is our population different?” The WSLH compared their patients with those used in the ATHENA trial, the study used by Roche to gain FDA approval for primary HPV testing. The combination of not getting regular screenings and follow up, along with their higher levels of infection and disease, put WSLH patients at a significantly higher level of risk for developing cancer. Ms. McCarthy noted that the initial results of the study were surprising and that our patients were more high risk than the general population. However, results demonstrate that they do not fit the mold that is being used to establish screening guidelines. We do not know if changes in screening algorithms and the shifting focus to primary HPV screenings will have adverse impacts for our patients. The study is ongoing and we now have over 250 high grade cases with HPV tests. The proportion of HPV negative has grown to over 60%. We are still awaiting genotyping results on these. We will continue to this study and will be publishing the final results later this year.

Dr. Kurtycz introduced Michele Smith, Program Director and Manager, Cytology Services, who has been working with Healthcare Education Training (HCET) to help our partners gain education and maintain women’s health services. Ms. Smith discussed the development of the digital colposcopy library which serves as a multidisciplinary education tool for clinicians and laboratorians. The guidelines for Pap smears continue to change. Around the year 2000, HPV reflex testing was available to test whether or not women had HPV positivity, but the test was only performed on abnormal cases. In 2006, Pap smear and HPV co-testing became the norm. In the future, we will most likely be focusing on the primary HPV test. The screening guidelines have become complicated stating that no women under the age of 20 should receive a Pap smear. Pap screening starts at age 21 with three year screening intervals. The WSLH worked with HCET and WI-DPH to develop a consolidated list of diagnostic guidelines. The pros of this program include strengthening the partnerships between the laboratory and clinic, ensure that all clinics are following the same screening guideline models, fostering continuous dialogue and education between the lab and the clinic and cost savings. Some obstacles from this are a decline in Pap smear volumes and patient visits. The main goals of the program are to provide access to care (testing for Pap & HPV, colposcopy, and surgical biopsy) in all 72 counties in Wisconsin. Our main goal is to develop and maintain a statewide community-based system for colposcopy services with expansion to rural areas as well. Some concerns for this expansion are training, equipment, competition, and competency. We need a way for clinics and clinicians to submit pictures to us in a de-identified manner so we can develop the colposcopy library for family planning clinics. This library will allow whole slide imaging, case studies, and surveys. Ms. Smith also presented several case studies describing Pap test pictures to

the Board. In all, the colposcopy library has been a large endeavor but has been very important in improving the lives of women throughout Wisconsin.

Item 8. NEW LABORATORY UPDATE

Dr. Brokopp introduced the new laboratory update to the Board. The DATCP laboratory moved into the new building in January 2014; however, the WSLH has run into some difficulties in securing occupancy. Dr. Brokopp introduced Russ Van Gilder from the Wisconsin Department of Administration Division of State Facilities. Some of the WSLH spaces in the new building are the most complicated components of the plan. As of today, all spaces are able to be occupied with the exception of the BSL-3 suites. The completion and commissioning of the BSL-3 suites has been slow and steady. The principle problems have been achieving reliable and consistent heating, air-conditioning, ventilation, and system controls. We are down to the last few physical adjustments. After that is complete, there will be some final programming of control systems. The budget for the project has been expended.

Dr. Brokopp introduced Darren Berger and Rebecca Moritz from UW Facilities Planning and Management. They are involved in ensuring the laboratory will be successfully registered by the federal government. This includes the Select Agent Program at the CDC. The amount of regulatory oversight of high containment laboratories is formidable. We have challenges ahead given that the budget has been liquidated and there is a lot of work that needs to be completed before the inspection which precedes approval for moving in. The UW has never registered a new facility that must meet the most current federal standards. Ms. Moritz mentioned that if the WSLH splits from the University of Wisconsin, there will be severe ramifications with regards to meeting select agent standards for biosafety and biosecurity.

Dr. Brokopp introduced Dave Guberud, our commissioning agent for the project from the firm Ring & DuChateau. Commissioning exists to ensure all of the systems perform up to a specified standard. The commissioning agent's responsibility is to document that this has happened. Mr. Guberud provided the definition of commissioning as a quality-focused process for enhancing the delivery of a project. The process focuses on verifying and documenting that the facility and all of its systems and assemblies are planned, designed, installed, tested, operated, and maintained to meet the owner's project requirements. Although the process has not happened as quickly as anticipated, we have made progress and are looking for failure scenarios to test the entire system in order to guarantee quality.

Item 9. FISCAL YEAR 2015 FIRST QUARTER REPORT

1) Marie Ruetten, Financial Manager, Wisconsin State Laboratory of Hygiene

Marie Ruetten, Financial Manager, WSLH, presented the FY15 second-quarter report. On an accrual basis, our FY15 year-to-date support and revenue is at \$20,556,177. The largest line items included in this amount are under laboratory services. With a year-to-date budget of \$21,219,170, we are under budget by \$662,993. We are under budget by \$688, 870 year-to-date with \$21,726,210 in expenses from a budget of \$22,415,080. Our net operating income is very close to budget at \$(1,170,033) from the budgeted amount of \$(1,195,910).

On a modified cash basis, capital expenses are added at \$755,910 YTD. Also, with reserve expenditures of \$990,910, we have a modified net operating income of \$55,696. Comparing FY15 to FY14, we have \$1,267,963 less in revenue. This has occurred primarily in agency and non-agency funds. Expenses have increased by \$547,026 compared to last year. In all, we have a net operating loss by \$1,814,989.

Our available working capital as of December 31, 2014 is \$7,059,394 compared to \$7,995,430 as of June 30, 2014. Cash-unrestricted has increased from \$9,064,175 on June 30, 2014 to \$10,843,649 on December 31, 2014. Our cash balance as of September 30, 2014 is \$12,537,979. Subtracting restricted cash, deferred revenue, and encumbered payables, we have an available unrestricted cash balance of \$2,138,345 as of December 31st, 2014.

Item 10. FORENSIC TOXICOLOGY UPDATE

1) Dave Webb, Director, Environmental Health Division, Assistant Director, Wisconsin State Laboratory of Hygiene

Mr. Webb introduced Amy Miles, WSLH Forensic Toxicology Manager, to give the forensic toxicology update to the Board. Since 2012, drug testing turn-around time has decreased by 82%. This translates from around 263 days to only 48 days. This is a strong testament to the hard work of our forensic toxicology staff. We have also reduced our coroner and medical examiner program turn-around time by streamlining testing workflow and devoting two chemists to closely monitor all cases. We have provided regional trainings, began a quarterly webinar, and obtained grant funding to provide trainings. Dr. Brokopp thanked Ms. Miles and her team for all their hard work on this significant accomplishment.

Item 11. LAB FEE COSTING PLAN UPDATE

1) Dr. Charles Brokopp, Director, Wisconsin State Laboratory of Hygiene

Dr. Brokopp provided the lab fee costing plan update to the Board for their input. In order to address this, a detailed cost assessment of a representative sample of all tests (102 tests at 7% account for 80% of test volume) was conducted. Results were analyzed based on a cost assessment of selected tests based on revenue (144 tests at 10% account for 80% of test charges). The direct costing variables analyzed included labor, materials, consumable supplies, depreciation and maintenance, interdepartmental expenses, and batch size. Once the cost is established, we will update the fee schedules to include the cost of building leases, information systems, utilities, administrative overhead. Dr. Brokopp presented the timeline for the project to the Board, with the goal of having a proposal completed for presentation to the Board in April.

Item 12. OCCUPATIONAL HEALTH 2015 FEE SCHEDULE

1) Dr. Charles Brokopp, Director, Wisconsin State Laboratory of Hygiene

Dr. Brokopp briefly presented the proposed fee schedule for the Wisconsin Occupation Health Laboratory (WOHL) on behalf of Steve Strebel, WSLH Occupational Health Division Director. We have not raised WOHL fees since January of 2011. Our fee revenue for WOHL is \$2.3M. We are recommending a 5% increase and expect to bring in an additional \$115,000. Most testing in this laboratory is for out of state contracts. The increase is needed to meet the FY15 budget. We will not be seeking approval for this increase at today's meeting, but will request that the WOHL fee increase be approved by the Board at the April meeting.

Item 13. STRATEGIC MAP UPDATE

1) Steve Marshall, Assistant Director, Wisconsin State Laboratory of Hygiene

Steve Marshall, Assistant Director, Wisconsin State Laboratory of Hygiene, provided the final strategic map update to the Board. The WSLH Strategic Leadership Team (SLT) and Board voted on objectives of the strategic map. Staff have also been assigned to categories for each objective to establish specific metrics and monitor progress throughout the year. There is a project charter for each objective detailing what needs to be done. Ultimately, this will be reviewed by SLT and Dr. Brokopp and shared with the Board. We plan to provide a yearly status update to the Board now that the plan has been implemented.

Item 14. CONTRACTS REPORT

1) Dr. Charles Brokopp, Director, Wisconsin State Laboratory of Hygiene

Dr. Brokopp presented the contracts report to the Board. There are no current contracts that the Board needs to approve. Contracts for this period include special projects with APHL totaling approximately \$380,000 worth of work. Two of these involve the WSLH Communicable Disease Division, one is a national influenza surveillance project, and another is a training project to improve the quality of antimicrobial susceptibility testing. We also have a contract to develop interactive training for newborn screening dried blood spot collection. Several miscellaneous contracts with Florida Power and Light, Puerto Rico Department of Labor, and the Nature Conservancy are also included in the report.

Item 15. DIRECTOR'S REPORT

1) Dr. Charles Brokopp, Director, Wisconsin State Laboratory of Hygiene

The next WSLH Board Meeting will take place on April 21st, 2015 at the 2601 Agriculture Drive location. At that meeting, the Board will have an opportunity to review the FY16 preliminary budget. Dr. Brokopp asked the Board to review the public and environmental health incidents in the Board packet along with the water systems report. Dr. Brokopp asked Dr. Pete Shult, Director, Communicable Disease Division, WSLH, to provide an update on public and environmental health incidents. Dr. Shult mentioned that we're still actively monitoring the Ebola virus. One element of the preparedness process was to ensure that testing is widely available. One year ago, testing for Ebola was only available in the United States through the CDC. Last fall, the WSLH was approved to perform Ebola testing. We had our first suspect case last week in Madison, WI. Other recent public health incidents we are currently addressing are mumps, flu (with a remarkably severe season due to a significantly less effective annual vaccine), and MERS-CoV.

Dr. Brokopp asked the Board to review the packet for public water system testing for the period of October 1st through December 31st 2014. Dr. Brokopp also noted that the WSLH is continuing its efforts in working on the VCFA's initiatives for employee engagement, inclusion, and diversity. Six workgroups have submitted reports and a lab-wide report is being drafted that includes a review of survey results, recommendations, implementation plans, and evaluation and monitoring metrics. Ultimately, there will be final input from staff, workgroups, SLT and the Board.

Dr. Brokopp concluded the meeting by mentioning the Governor's budget proposal to the Board. Dr. Brokopp said that we will be working with the necessary parties going forward and will be determining what needs to be done to guarantee our success in continuing to serve the people of Wisconsin. There are many concerns that will need to

be addressed in the future. Dr. Brokopp noted that these conversations will continue and stressed to the Board the importance of being aware of the issues at hand. Dr. Brokopp mentioned that he will provide an update at the April meeting.

Vice-Chair Robert Corliss made a motion to adjourn meeting at 4:00 P.M. **Jeffery Kindrai** seconded the motion. The motion passed unanimously and the meeting was adjourned.

Respectfully submitted by:

A handwritten signature in black ink that reads "Charles D. Brokopp, DrPH". The signature is written in a cursive style with a large, stylized initial 'C'.

Charles D. Brokopp, DrPH
Secretary, Wisconsin State Laboratory of Hygiene Board of Directors