

**Wisconsin State Laboratory of Hygiene
Board of Directors Meeting
September 18, 2024
1:00 pm – 4:00 pm**

APPROVED MINUTES

Wisconsin State Laboratory of Hygiene Board of Directors Meeting

Wednesday, June 26, 2024

<1:00-4:00 pm>

MEMBERS PRESENT:

- | | |
|-----------------------------------------------------------------------|----------------------------------------------------------------------|
| <input checked="" type="checkbox"/> Chair Greg Pils (DNR) | <input checked="" type="checkbox"/> Jeffery Kindrai |
| <input checked="" type="checkbox"/> Vice Chair Dr. Christopher Strang | <input checked="" type="checkbox"/> Hasmik Mkrtchyan |
| <input checked="" type="checkbox"/> Secretary Dr. James Schauer | <input checked="" type="checkbox"/> Zana Sijan (WDNR alternate) |
| <input checked="" type="checkbox"/> Dr. Robert Corliss | <input checked="" type="checkbox"/> Becca Fahney (WDNR alternate) |
| <input type="checkbox"/> Dr. Jon Audhya (SMPH) | <input type="checkbox"/> Paula Tran (DHS alternate) |
| <input checked="" type="checkbox"/> Dr. Mark Werner (DHS) | <input type="checkbox"/> Anna Benton (DHS alternate) |
| <input checked="" type="checkbox"/> Jessica Blahnik | <input checked="" type="checkbox"/> Dr. Sheryl Bedno (DHS alternate) |
| <input type="checkbox"/> Gina Green-Harris | <input checked="" type="checkbox"/> Andrea Poehling (SMPH alternate) |
| <input checked="" type="checkbox"/> Gil Kelley | |

WSLH STAFF PRESENT:

- | | |
|-----------------------------------------------------|-------------------------------------------------------|
| <input checked="" type="checkbox"/> Dr. Errin Rider | <input checked="" type="checkbox"/> Mark Conklin |
| <input checked="" type="checkbox"/> Allen Benson | <input checked="" type="checkbox"/> Camille Danielson |
| <input checked="" type="checkbox"/> Kevin Karbowski | <input checked="" type="checkbox"/> Tip Vandall |
| <input checked="" type="checkbox"/> Jan Klawitter | <input checked="" type="checkbox"/> Jim Sterk |
| <input checked="" type="checkbox"/> Nancy McLean | |
| <input checked="" type="checkbox"/> Steve Strebel | |
| <input checked="" type="checkbox"/> Dr. Al Bateman | |

GUESTS PRESENT: Not applicable

PROCEDURAL ITEMS

Item 1. ROLL CALL

WSLH Board Chair Greg Pils called the meeting to order at 1:02 pm.

At 1:02 pm, WSLH Executive Assistant Sara Anderson initiated and conducted the roll call of the Board members. All Board members or their designated representatives were present except for those excused. INDICATED ABOVE

ADDITIONAL COMMENTS: New DNR Board Member Alternate Rebecca Fahney also attended this meeting.

Item 2. APPROVAL OF MINUTES

At 1:03 PM, WSLH Board Chair Greg Pils entertained a motion to approve the March 2024 meeting minutes as submitted. Vice Chair Dr. Christopher Strang moved for approval and Jeff Kindrai seconded. A voice vote to approve the minutes for the record was passed unanimously and accepted.

Item 3. REORGANIZATION OF AGENDA

Not applicable for this meeting.

Item 4. PUBLIC APPEARANCES

No public appearances were made amidst this meeting.

Item 5. BOARD MEMBERS' MATTERS

ANY BUSINESS FROM BOARD MEMBERS?

New WSLH Board Member Hasmik Mkrtchyan introduced herself to the rest of the board, mentioning first and foremost that she is both excited and honored to be brought on as part of the board. She continued by providing a brief background on herself, sharing that her graduate work was at George Washington University and has worked in manufacturing for 12 years with experience working in a laboratory setting. She stated her passion is in the realms of lab automation in a biotech company. The current board members took turns introducing themselves and shared their roles and occupations and their time served on the board. (Andrea Poehling spoke on behalf of herself and absent board member Dr. Jon Audhya). Local Health Department Representative Jeff Kindrai announced he will be retiring from his position as Grant County Health Officer this summer, so the June 26th WSLH Board Meeting is his last. WSLH Director Jamie Schauer and WSLH Board Chair Greg Pils congratulated Mr. Kindrai on his retirement and thanked him for his long service on the WSLH Board. Mr. Kindrai was appointed

to the WSLH Board in 2009 and will contact the Wisconsin Association of Local Health Departments and Boards (WALHDAB) so they can send a recommendation for his Board replacement to Governor Evers' office. Mr. Kindrai thanked everyone for a wonderful time spent on the board and noted that it has been an amazing experience witnessing the board evolution over the course of so many years. He also mentioned two issues relating to rabies testing. First, he said that some local health departments are having difficulties getting animals into veterinarian offices for observation after a biting incident. The local health officers sometimes have to get their county corporation counsels involved. He said some local health departments are working on a pilot program to allow the local health departments to do observation programs. Second, he said the cost of shipping rabies samples to the WSLH is becoming prohibitively expensive. His health department recently shipped a couple of bats for rabies testing and the cost was \$100+. Currently, the WSLH does not cover the cost of shipping for rabies samples. WSLH Communicable Disease Division (CDD) Director Dr. Al Bateman mentioned that the WSLH contracted courier could be a possibility, but funding to pay for the shipping would need to be found first as there is no current funding for this use of the courier.

BUSINESS ITEMS:

Item 6. **FY25-FY27 Strategic Plan**

WSLH Director Dr. Jamie Schauer provided a brief overview of the WSLH Strategic Plan, noting that WSLH programs are driven by Wisconsin State Statute, expectations from Wisconsin state agencies and local health departments, and federal agencies. Dr. Schauer said the initiatives of the Strategic Plan are at a high level and that the plan is intended to improve how the WSLH implements its programs and efforts to achieve the WSLH Mission. After a brief overview of the plan's initiatives – featuring data modernization, scientific advancement, clinical biomonitoring, outreach, culture/belonging, space, and advancing the public health missions of SMPH and UW-Madison – Dr. Schauer requested formal approval of the Strategic Plan by the board at the start of the fiscal year on July 1, 2024. Dr. Schauer mentioned that a longer-term facet of the utmost importance is additional space (at the Ag Drive location in particular). He additionally mentioned that the Public Health Missions of SMPH are closely connected to the new FDA regulations on laboratory developed tests (LDTs) that will have a significant impact on many of our clinical labs. In order for our labs to do diagnostic testing, there will need to be some form of evolution with these new FDA rules. Lastly, Dr. Schauer mentioned how data modernization (a highlight of the Strategic Plan) is important and a key component in how we interact with our partners. At 1:19 pm, WSLH Board Chair Greg Pils made a motion to approve the FY 25-27 Strategic Plan. This motion was seconded by Vice Chair Dr. Christopher Strang, and a voice vote to approve the WSLH Strategic Plan was passed unanimously and accepted.

Item 7. **Financial Report**

Kevin Karbowski (CFO) presented the financial report for the first ten months of the fiscal year. Net Operating Income was a gain of \$815,462 compared to an expected (budgeted) loss of \$779,967. Revenue was \$56,092,673 compared to an expected \$52,752,712. Expenses were \$55,277,211 compared to an expected \$53,532,678. Revenue was over budget due primarily to increased clinical activity. Expenses were over budget, owing primarily to increased supplies tied to the aforementioned clinical activity.

Mr. Karbowski presented a proposed break-even budget for FY25. Mr. Karbowski also requested that the budget include a general 6% price increase to be implemented between October 1, 2024 and January 1, 2025. Mr. Karbowski noted that there would be tests that may change at a different rate, but these exceptions would be based on business needs and rare. An example would be prices that are set for a specific contract period. At 1:48 pm, WSLH Board Chair Greg Pils made a motion to approve the FY25 Budget as presented and a general 6% fee increase in FY25. The motion was seconded by Jeff Kindrai, and a voice vote to approve the FY25 Budget and the 6% fee increase was passed unanimously and accepted.

The 2025-2027 Biennial state budget was discussed next. Dr. Schauer stated that he would like the Board to support the Wisconsin Department of Administration's 2025-2027 biennial budget request to construct and develop an additional WSLH wing at the WSLH Agriculture Drive Facility. Dr. Schauer explained that the WSLH is slowly phasing out of the Henry Mall location on campus that was built in the 1953 as it is not on the UW-Madison campus master plan— with a suggested timeframe effectively evacuating Henry Mall within a 10 to 15 year timespan. DOA wants to put in a state budget request for funding to construct an additional wing on the Ag Drive Building. WSLH Director of Clinical Laboratory Services Dr. Errin Rider informed the Board that DOA is working on getting a bid for a design firm, with design and costing hopefully completed by November 2024. At 1:58 PM, Jeff Kindrai made a motion to rescind the March 2024 approval of WSLH Biennial Budget Request for a recurring increase in GPR to cover additional rent expenses and support the DOA's biennial budget request to construct and develop an additional wing at the WSLH Agriculture Drive facility. This motion is seconded by WSLH Board Chair Greg Pils, and a voice vote to approve the biennial budget was passed unanimously and accepted.

Item 8. **Contracts Report**

WSLH Financial Manager Tip Vandall shared information regarding the summary of contracts executed since the March 2024 Board Meeting. Ms. Vandall informed the Board that the grand total estimates are around \$1 million, with 6 contracts that were entered and signed in the past 3 months. For reference, a short-term contract is 3-4 months while the other standard contracts are about 12 months. There are two annual renewal contracts as well which are estimate at \$675,000.

Item 9. Directors Report

Director of Clinical Laboratory Services Dr. Errin Rider shared information about the new FDA rules for Laboratory Developed Tests – or LDTs for short. On May 6, 2024, the FDA published, “a final rule to amend its regulations to make explicit that in vitro diagnostic products are devices under the Federal Food, Drug, and Cosmetic Act – including when the manufacturer of the IVD is a laboratory.” Due to this publication, all clinical and public health laboratories must now comply with the FDA regulations and requirements for medical device manufacturing for any new laboratory-developed tests. It should be noted that in the past the FDA allowed enforcement discretion of LDTs implemented in clinical and public health laboratory settings. Dr. Rider gave a brief history surrounding FDA/LDT regulations, sharing that the Medical Device Amendments act was passed in 1976 establishing class I (low risk), class II (moderate risk), and class III (high risk) regulations for medical devices. In 2014, the FDA issued draft guidance arguing it had the authority to regulate LDTs, and by 2018-2022 the VALID Act (proposed but not passed) would have provided the FDA explicit oversight over LDTs. Dr. Rider informed the board that on May 6, 2024 the FDA offered a 4-year phase-in process for all laboratories; with year 1 requiring reporting for MDRs and Corrections/Removals, year 2 requiring registration and listing/labeling/investigational device exemption, year 3 requiring quality systems requirements, and year 4 requiring PMA applications for high-risk LDTs and De Novo submission for low to moderate risk LDTs. Dr. Rider added that it’s important to note that any tests implemented on May 6, 2024 or after must meet requirements for Years 1 through 4, including all Quality System Requirements in year 3. The Cost of submission is not just the fees. The cost of submissions to the FDA varies by class. Class III includes application fees of \$485,000 per test, with an estimated total cost of around \$4.5 million. Classes I and II includes application fees of \$21,760 per test, with an estimated total cost of \$250,000. The FDA stated that they would be reevaluating these fees. Dr. Rider shared some points of emphasis surrounding exemptions for public health under these new circumstances. For example, Emergency Use Authorization follows the current path of FDA clearance, and the FDA may authorize labs to implement EUA tests in an emergency (as was the case during Covid-19). Pathway for public health laboratories to respond immediately to Chemical and Biological emergencies as long as testing does not continue past 12 months falls under exemption 564. Unfortunately, these exemptions are only for emergency testing and do not cover Newborn Screening and other testing of public health importance. Dr. Rider stated that while guidance that the FDA released is not completely clear, the WSLH will look to CDC and APHL in order to understand better what labs can do in this interim period. Dr. Rider said that some actions to stop implementation include two bills in Congress and a lawsuit filed by the American Clinical Laboratory Association. The upcoming federal elections may or may not affect implementation of the regulations.

Key Public Health Notices – Camille Danielson

WSLH Environmental Chemistry Programs Director Camille Danielson shared a series of key public health and environmental notices from the period of March 25 through June 11, 2024. Examples cited included –

On March 14th, WI Governor Tony Evers signed the 2023 Wisconsin Act 108 into law making significant changes to E-Cycle Wisconsin. One significant component of this law directs the DNR to create rules for ‘good faith progress’ towards meeting a manufacturer’s recycling target. This law also changes the formula used to set electronics manufacturers’ annual recycling targets and expands the definition of ‘peripheral.’

The EPA announced new enforceable federal standards for PFAS in drinking water that includes a new enforceable MCL of 4.0 parts per trillion individually for PFOA and PFOS and 10 ppt individually for PFNA, PFHxS, and GenX and PFBS present in a mixture.

There is a previously undetected parasite discovered in wild Wisconsin trout. *Myxobolus Cerebralis* is a microscopic parasite that damages the cartilage and nerve tissue of trout and salmon and has been known to cause whirling disease.

The Wisconsin Office of Children’s Mental Health released a fact sheet on the mental health impact of school shootings, stating that children who survive school shootings have twice as many pain disorders, are 68% more likely to have a psychiatric diagnosis, and are 144% as likely to develop a substance use disorder than those who did not experience a shooting.

On April 17th, the DNR approved stewardship funding for Friends Grants to 24 nonprofit organizations for improvements at DNR properties across the state. The State Building Commission approved funding for 29 projects using Stewardship grants.

Law enforcement agencies awarded grants from state opioid settlement funds. Specifically, twelve tribal nations, county and municipal law enforcement agencies received grants from the Wisconsin Department of Health Services for projects to prevent and reduce the dangers of opioid use.

The DNR published its 2023 Fish Stocking Summary – with over 6 million fish stocked across Wisconsin waters.

Five Crisis Stabilization facilities across Wisconsin were funded by the Department of Health Services. The centers provide a dedicated location for a level of care for those who are no longer able to stay in their community safely, but don’t need to be hospitalized.

Public Relations Report – Jan Klawitter

WSLH Communications Manager Jan Klawitter provided the Board with highlights of WSLH staff activities and accomplishments. Items noted were that on April 5th, WSLH Communicable Disease Division (WSLH CDD) scientists confirmed a positive measles case in a Wisconsin

resident. This initiated a large multi-county and state public health response. There was no further spread or cases to date. In late March 2024, the USDA announced that H5N1 avian influenza had been detected in cattle herds in multiple states throughout the country. In preparation for responding to this development, WSLH CDD worked with the Wisconsin Veterinary Diagnostic Laboratory (WVDL) to stay aware of recent findings in cows, worked with WVDL to initiate testing of cats with neurologic symptoms who test negative for rabies, and validated a higher throughput nucleic acid instrument for testing. The WisCon occupational health onsite safety and health consultation program performed outreach in early June to Wisconsin employers who may be impacted by H5N1 avian influenza providing CDC guidance on how to protect affected workers. On February 21st the WSLH honored 27 staffers with Quality and Safety Awards. The Association of Public Health Laboratories held its annual scientific conference in Milwaukee with 30+ WSLH scientists giving presentations and/or posters at the event. On May 9th, the WSLH hosted a tour of the Ag Drive facility for conference attendees. The WSLH also worked with the Madison Metropolitan Sewerage District to provide a separate wastewater surveillance focused tour. Lastly, Wisconsin Governor Tony Evers proclaimed May 22, 2024 as “Wastewater Professionals Appreciation Day.” The proclamation and statewide communications were the result of joint efforts by wastewater surveillance and communications staff at the WSLH and the WI Department of Health Services to laud the efforts of wastewater professionals who submit samples for wastewater surveillance testing. A celebratory event was also held at the Madison Metropolitan Sewerage District.

Adjourning

At 2:55 pm, Jeff Kindrai entertained a motion to adjourn. Motion to adjourn seconded by WSLH Board Chair Greg Pils. All present voted to adjourn the board meeting. WSLH Board Chair Greg Pils adjourned the meeting at 2:56 pm.