





Chemistry and the Law NEWSLETTER

CHAIR'S MESSAGE KATIE RUBINO



The chemistry and the law (CHAL) division is excited to be gearing up for another national meeting. We look forward to our continued commitment to serving the chemical community in providing the much-needed legal advice in their pursuit of advancement in the chemical sciences.

I am deeply thankful to all the participation we had at the Fall 2022 ACS National Meeting in Chicago, Illinois. Presentations included a

wide area of legal topics including tips for strengthening patent rights based on recent Federal Circuit Decisions, understanding who is an inventor on a patent, the role of technical expertise needed in patent litigation, trade secret protection in the pharmaceutical industry, how chemistry serves in forensic science, and factors to consider when licensing intellectual property.

This year, the CHAL division would like to continue to recruit and welcome new members. We are particularly interested in collaborating with anyone interested in learning more about the crossroads of chemistry and the law. We aim to continue to program across various industries and technology sectors including practical legal advice for

INSIDE THIS ISSUE

COUNCILORS' REPORT 2

SCHEDULE OF EVENTS

CHAL FEATURED REPORT

CALL FOR A WEBMASTER

EXECUTIVE COMMITTEE

13

12

6

chemical start-ups, forensic applications of the law, FDA regulatory issues, research agreements, and many more sensational topics.

The ACS Spring 2023 National Meeting will be held as an in-person/oral hybrid meeting in Indianapolis, Indiana. CHAL's Executive Committee will hold its monthly virtual meeting on Sunday March 26th at 6:00 pm Eastern. The meeting is open to all who are interested in attending. Our monthly meetings typically occur on the third Tuesday of every month at 3:00 pm Eastern. Please feel free to reach out for more information. I look forward to seeing everyone soon.

Katie Rubino

COUNCILORS' REPORT DR. JAMES CARVER & DR. BRIAN

MEADOWS

ACS Hybrid Meeting in Indianapolis

The Spring ACS Meeting (2023), scheduled for Indianapolis, IN, again will be a hybrid meeting. Most of the governance function will be available on a hybrid basis.

For 2023, the President is Judy Giordan, the President-Elect is Mary Carrol, the Past-President is Angela Wilson.

The nominations for President-Elect for 2024 are Mary Engelman (Retired, Eastman Chemical Company), Dorothy Phillips (Retired, Waters Corporation), and Florian Schattenmann (Cargill Inc.). Council will select two candidates from

these three nominees at the Council meeting on Wednesday, March 29, 2023.

The Nominees for District Director for District III are Benny C. Chan, Diane Krone, Helen (Bonnie) A. Lawlor, and Stephanie J. Watson. The Nominees for District Director for District VI are Janet L. Bryant, Susan Kauzlarich, Jeannete M. Van Emon, and Richard V. Williams. Council will select two candidates from the nominees from each District at Council on Wednesday, March 29, 2023. Councilors residing in Districts III and VI will be sent ballots once the candidates are selected.

The Candidates for Directors-at-Large are Wayne E. Jones, Jr., Daniel Babonovich, Carolyn Ribes, and Joseph P. Stoner. From these Candidates, two Directors-at-Large will be selected by the Councilors at the Council meeting on Wednesday, March 29, 2023.

From the elections at the Fall 2021 ACS meeting, the following individuals were elected:

- COUNCIL POLICY COMMITTEE Raychelle Burks, James C. Carver, Anne M. Gaffney, Lydia E.M. Hines, and Frankie K. Wood-Black
- COMMITTEE ON COMMITTEES William F. Carroll, Jr., Ella L. Davis, Carmen Gauthier, Thomas H. Lane, and Jason E. Richier
- **COMMITTEE ON NOMINATIONS AND** ELECTIONS Michelle V. Bauchanan, Alan B. Cooper, Kelly M. Elkins, Ellene Tratras Contis, and Kathryn E. Uhrich
- 2022 PRESIDENT-ELECT Judith C. Giordan



- DIRECTOR, DISTRICT II DIRECTOR Kimberly Agnew-Heard
- DIRECTOR, DISTRICT IV Lisa Houston
- DIRECTOR-AT-LARGE Malida Jeffries-El and Will E. Lynch

In addition, ACS has hired a new CEO, Albert G. Horvath, formerly the chief financial officer for ACS. His focus is as follows:

GOAL 1—Provide Information Solutions – Deliver indispensable chemistry-related information solutions to address global challenges and other issues facing the world's scientific community.

GOAL 2— Empower Members and Member Communities – Provide access to opportunities, resources, skills training, and networks to empower our global members and diverse member communities to thrive.

GOAL 3— Support Excellence in Education – Foster the development of innovative, relevant, and effective chemistry and chemistry-related education.

GOAL 4— Communicate Chemistry's Value – Communicate — to the public and to policymakers — the vital role of chemical professionals and chemistry in addressing the world's challenges.

GOAL 5—Embrace and Advance Inclusion in Chemistry – Promote diversity, equity, inclusion, and respect; identify and dismantle barriers to success; and create a welcoming and supportive environment so that all ACS members, employees, and volunteers can thrive. The focuses of the ACS President Judy Giordan will be promoting Chemists as a trusted voice in the chemical sciences, strong advocacy on behalf of ACS for chemical sciences and chemical scientists/engineers, and continued support for Diversity, Equity, Inclusion and Respect (DEIR).

Initiatives before Council

- Review of Future Council Representation
- Review of Future Operations of Council (Hybrid Meetings)
- Review of non-Councilor Travel Reimbursement Program

Petitions before Council

- A Petition to amend the Standing Rules related to the duties of the Council Policy Committee regarding removal of Councilors.
- A Petition to amend the Name and Duties of the Committee on Environmental Improvement to add "Sustainability" to the name and duties.
- Petition to allow for the Committee on Nominations and Elections options in conducting elections.
- Petition for a 2024 schedule of Membership. (See some of the key features below)

I. BASE DUES

The base dues rate shall be \$160.

II. BENEFITS PACKAGES

The American Chemical Society offers multiple benefits packages for its members, affiliates, and associates. As assigned in this Schedule of Membership, eligibility for receiving these



packages varies across membership types. The offered packages are as follows.

1. Premium Package

The Premium Package contains the full range of privileges and benefits as offered by the SOCIETY.

2. Standard Package

- a. The Standard Package contains the full range of privileges and benefits as offered by the SOCIETY except that it does not provide:
 - (1) Any ACS Publications or author benefits including but not limited to universal publications accesses and reduced subscription rates as approved by the Board of Directors.
 - (2) Any Chemical Abstracts Service (CAS) benefits including but not limited to complimentary search activities.
 - (3) Discounted registration rates for ACS meetings, workshops, and continuing education courses where allowable.
- (4) Access to the ACS webinar recording library. b. The Standard Package contains digital access to the official organ of the SOCIETY. It does not provide access to the print edition.

3. Basic Package

The Basic Package shall include only the privileges and benefits described below:

- a. Receipt of SOCIETY newsletters.
- b. Receipt of weekly, abbreviated digests of the official organ of the SOCIETY.
- c. Five additional downloadable articles from the official organ of the SOCIETY beyond the number permitted for non-members of the SOCIETY.
- d. Access to discounts on personal services offered by external SOCIETY partners.

III. DUES CATEGORIES

1. Regular Members

- a. Regular Members may select the **Premium Package**. The dues rate for Regular Members with the Premium Package shall be the base dues rate.
- b. Regular Members may select the **Standard Package**. The dues rate for Regular Members with the Standard Package shall be one-half (1/2) of the base dues rate.
- c. Regular Members are eligible for those discounts as outlined elsewhere in the Schedule of Membership.

2. Graduate Student Members

A member who is a full-time graduate student majoring in a chemical science or in a related field shall be entitled to the **Premium Package** at a rate of eleven thirty-seconds (11/32) of the base membership dues.

3. Student Members

Undergraduate students may become STUDENT MEMBERS of the SOCIETY, in accordance with the ACS Governing Documents. They shall be entitled to all privileges of membership except that of holding an elective position of the SOCIETY.

A STUDENT MEMBER, upon affirmation to the Chief Executive Officer of qualification for such status, shall be entitled to receive the **Premium Package** at a rate of five thirty-seconds (5/32) of the base membership dues. The dues so determined shall be rounded to the nearest whole dollar amount.

A STUDENT MEMBERS shall receive digital access to the official organ of the SOCIETY.



A STUDENT MEMBER shall not receive print access to the official organ of the SOCIETY.

4. Society Affiliates

The base dues rate or the Standard Package at one-half (1/2) of the base dues rate. Society Affiliates shall have no vote in the national affairs of the SOCIETY and shall not be eligible for any elective office in the SOCIETY.

5. Community Associates

Community Associates share common connections to the SOCIETY such as participating in webinars, subscribing to, publishing in, or reviewing manuscripts for ACS journals, or participating in other SOCIETY-sponsored programs, events, or services.

- 6. Retired Members
- 7. Emeritus Members

Petition for Consideration (To be up for a vote at the fall ACS National Meeting)

Petition to Add an International Representative on the Board of Directors.
 This petition requires amending the Constitution, the Bylaws and the Standing Rules.

Budget and Finance

The Society's 2023 financial performance was excellent. The Society ended 2022 with a net contribution from operations of over \$40 million, a bit down from the record contribution of 2021. Once again, ACS ended the year in compliance with all of the five Board-established financial guidelines.



SPRING 2023 SCHEDULE OF EVENTS

Sunday March 26 AFTERNOON SESSION: PRACTICE TIPS TO STRENGTHEN YOUR PATENTS BASED ON RECENT HIGH COURT OPINIONS

2:00-2:05pm ET

Introductory Remarks

Presenter: Matthew Hlinka

Location: Room 123 (Indiana Convention Center)

2:05-2:35pm ET

Strengthening your future patent rights in light of recent federal court decisions

Presenter: Dr. Xavier Pillai; Dr. Andrew Berks

Location: Room 123 (Indiana Convention Center)

2:35-3:05pm ET

Federal Circuit continues to illuminate aspects of US patent law

Presenter: Carol Nielsen

Location: Room 123 (Indiana Convention Center)

EVENING SESSION: CHAL EXECUTIVE COMMITTEE MEETING

6:00-7:00pm ET

All are invited to attend

Location: Room 123 (Indiana Convention Center)

Monday March 27

MORNING SESSION: HOT TOPICS IN IP LAW

8:00-8:05am ET

Introductory Remarks

Presenter: Matthew Hlinka

Location: Room 123 (Indiana Convention Center)

8:05-8:35am ET

Patent strategy 101 for universities, startups, and other organizations with limited budgets

Presenter: Zachary Wiersma

Location: Room 123 (Indiana Convention Center)

8:35-9:05am ET

Extraterrestrial intellectual property law: Current status and future trajectory

Presenter: Gary DeBoer

Location: Room 123 (Indiana Convention Center)

9:05-9:35am ET

How you draft it matters

Presenter: Carol Nielsen

Location: Room 123 (Indiana Convention Center)

9:35-10:05am ET

Role of genus claims in protecting chemical and biotechnology inventions

Presenter: Roy Issac

Location: Room 123 (Indiana Convention Center)

10:05-10:20am ET

Intermission

10:20-10:50am ET

Collaborating to develop pharmaceuticals: Key IP diligence questions and contract provisions.

Presenter: Shana Cyr

Location: Room 123 (Indiana Convention Center)



SPRING 2023 SCHEDULE OF EVENTS

Monday March 27

10:50-11:20am ET

After the rainbow: Consequences of insufficient safety instruction

Presenter: Samuella Sigmann

Location: Room 123 (Indiana Convention Center)

11:20-11:50am ET

Future of patent enablement: An update on the Supreme Court and practical tips for practitioners

Presenter: Kenneth Guerra

Location: Room 123 (Indiana Convention Center)

AFTERNOON POSTER SESSION

12:00-2:00pm ET

Fluorescent yellow method for collecting fingerprints on porous materials

Presenter: Mikayla Sorensen

Location: Hall F-H (Indiana Convention Center)

EVENING SESSION

6:00-8:00pm ET

CHAL Reception

Location: Hall F-H (Indiana Convention Center)

Report of an adventure in forensic chemistry -with defense lawyer-biased opinion¹-

M. Grossman.²³

As a criminal defense lawyer in Toronto, I have argued forensic chemistry issues — over quite a few years — to try to persuade court-presiding jurists that drug cases under the Canada *Controlled Drugs & Substances Act* were inadequately proven by Crown counsel. My arguments were never successful that *Certificates of Analyst* of the Health Canada DRUG ANALYSIS SERVICE were inadequate as scientific proof.

Canadian law and constitution, as I have reluctantly come to understand, allows Parliament to enact anti-science legislation – *CD&S Act*, s.51 – that allows the government to impose bad science to convict criminally accused people. It is bad science, if only for the reason that the science remains unexplained; there is no proper scientific report.

Canadian law is essentially that the *qualitative* declarations of DAS *Certificates* are not to be questioned; they are to be recognized, by operation of law, as conclusive evidence of what they declare; the data they impose are to be regarded as the legal truth before the court, notwithstanding science otherwise. I have opined about this in CHAL presentations at ACS Meetings, and in this *newsletter*; and subsequently in an opinionated essay chapter⁴ in my recently published book.⁵

So, what's a criminal defense lawyer – also a chemist — to do. There is a lawyerly requirement to vigorously defend a client who is *presumed innocent*, until and unless a judge might decide otherwise, but only after hearing procedurally correctly presented evidence, for *proof beyond a reasonable doubt*. with no requirement on the accused to prove innocence. This is part of the concept of rule of law in Canada, USA, and UK.

So, as one attempt to not be stopped by CD&S Act, s.51, I have looked forensically elsewhere.

I have noticed that *DAS Certificates of Analyst* usually report only *qualitatively* what the substance is – not how much, nor concentration. Nor ionization, nor chirality. The *quantity* measurements are determined from a Police process, and not by DAS. Those Police data (observed at a police facility) would be from before DAS (at another location) became involved, and therefore not under the jurisdiction of the s.51 distortion of the normal law of evidence. Those Police data are therefore normally disclosable, in ways that DAS data are not.

https://www.degruyter.com/document/doi/10.1515/9783110718812/html



¹ (25 September 2022.)

² M.G., B.S., Ph.D., LL.B., Barrister & Solicitor, of the Ontario Bar, Toronto, Canada. M5W 1P3 d441267@yahoo.ca

³ ACS member since 1968; CHAL since 1981; editor of this newsletter 2001-2005.

⁴ Chapter 10. "Essay – biased opinion – polemic. ... [CD&S Act,] – *ipse dixit*."

⁵ M.G., Forensic Chemistry Fundamentals, De Gruyter, Berlin, 2021.

Those police data are typically lists of mass measurements in grams (called "weight" by Police and Crown counsel). The defense litigation then would be concerned with questioning the reliability of Police-reported mass measurements.

The Police forensic mass determination data -- from Police process, and not by DAS -- are of significant importance for evidence, because the quantities of illegal drug are relevant to severity of sentence, if there would be conviction.

But, those Police forensic data have additional significant importance: To persuade the presiding trial Judge that the accused was criminally in possession of a drug substance, Crown counsel would have to prove actual quantity beyond so small that the court should consider it as not zero -- *de minimis non curat lex*. To prove this requires reliable forensic data. In this context, it should be noticed that modern GC-MS instrumentation likely used by DAS might have sensitivity in the range of 10-9 mol -- that would be *de minimis* at the alleged crime scene.

Thus, while there would be evidence of some substance seized by Police, if it is not presented as a forensic scientific examination of mass, proportion and selection, the court should not accept it as *proof beyond a reasonable doubt* -- the criminal law test -- of any quantity significantly above zero. And, even if the bulk mass as reported of what was seized were to be accepted, there would still be no indication of proportion of criminalized drug within that bulk.

These matters are not trivial, but require sophisticated scientific procedure and explanation. Thus, the litigation comes to scrutinize the science of the mass determinations of the police-seized items of evidence. Resulting discussions of the related physics, analytical chemistry, instrumentation engineering, instrument operating manuals, and procedures do not appear to be too well received by Crown counsel. But from a defence-biased prospective, that's what these cases mostly come to be about.

For purposes of this discussion, these criminal case litigations start with disclosure to defence counsel. Police-measured amounts -- "weight" (grams) -- are reported. Scientific measurement and error controls are not reported, and might or might not exist. Further and forensic disclosure is requested – including concerning:

- Description of the device used to measure mass manufacturer, supplier, model number, catalogue number, serial number?
- Was it a "device" or "weighing machine" within the meaning of the Canada Weights & Measures Act, s.2? Inspection Sticker certificate issued by Measurement Canada -- W&M Act, s.8?
- Other inspection or certification?
- Operating manual or literature, or other publication reference?

See: Bruce A. MacFarlane, DRUG OFFENCES IN CANADA, CHAPTER 21, "DE MINIMIS NON CURAT LEX," pages 447-467; Canada Law Book Limited, Toronto, 1979. ISBN 0 88804 007 5.



- Maintenance log?
- Calibration?
- Error statement?
- Training documentation of operator. Accreditation. Curriculum vitae?
- Sample preparation & handling. Temperature, humidity, air currents? Mass of container (polymer bags, etc.)? *Tare*?
- Standard operating procedures (as SOP documents), or similar documents.?
- SOPs for the recording and tabulation of taken-in data. And the checking and rechecking thereof?
- The Health Canada "Drug Analysis Service Client Manual for Exhibit Submission and Analysis."? (DAS policy and practice would likely prevent disclosure of this document to Defense counsel.)
- Quality assurance regime? QA manual? ISO 17025 accreditation? ISO 9000 registration?
- Sampling plan?
- Was ambient moisture taken into account? Hygroscopic evidence items?
- Was the likelihood of the evidence item as ionized taken into account? For example, the possible presence or absence of a chloride ion Cl-, and an additional hydrogen atom H? (Cl-+ H 35.453 + 1.008 = 36.461 g/mol).
- Was any estimate made for chiral alternatives?
- What precautions were taken to protect the measured samples from contamination from unrelated other samples, or mix-up?
- What precautions were taken to protect the Police supply of Health Canada exhibit envelopes and containers from contamination?
- Formal reports of the forensic measurements & findings? Error statements?
- Did the mass measuring device have computer compatibility to generate an electronic record of the measurements? Are there such electronic records? Was there on-paper print-out?

Scientists would regard the above as mostly routine for the making of scientific measurements. Crown counsel and police would be puzzled by much of the above. Some of the above would eventually be answered. Perhaps the single most important disclosure component would be the device Operating manual, for which an internet link could be easily provided.

The essential concept issue would be how to regard the measuring process. It is not just noting-down read-out numbers as they appear. It is really an actual scientific forensic measurement process, with all the appropriate precautions, controls, and explanations. This would be the basis of the defense cross-examination of police personnel who made, recorded, and reported the measurements. The device operating manual would be a ready source for cross-examination questions.

In my experience so far, I have never gotten to the stage of police personnel testifying about the mass measurements. The few of these cases I have been involved with, in my small law practice, have either

been resolved without trial testimony, or are cases still on-going.

If it would appear from trial testimony that the police measurements were not scientifically sufficient, then I would anticipate eventually arguing to the Judge that the mass data should not be regarded as significantly credible evidence. Argument would include that enough of the uncertainties were too large for conviction *beyond a reasonable doubt* – the criminal law test.

In one of my cases, I had engaged a university chemical engineering professor to testify as an expert witness, to explain to the court as to how scientific mass measurements should be done. I anticipated referring to that expertise in argument to the Judge as to the inadequacy of the police measuring process. As it actually turned out, we never got that far; the case was resolved at the beginning of the second trial day, before any forensic evidence was heard.

I would like to conclude by commenting that the opinions above about challenging Police-measured criminalized drug quantities are of case-specific limited legal importance; and should, in the future, be easily addressed by improved police procedures. Of more importance, in a policy sense, while I assume that Crown counsel and Police are acting in good-faith, I would offer that Canada would benefit if the legal education of lawyers and Judges included more science, and better encouraged appreciation of science concepts. At least as a courtesy, people in jeopardy of prison, deserve clued-in decision-making on science issues, by those in authority who might send them there

And, of rather more importance, in a policy sense, is the unfairness that *CD&S Act* s,51 allows and encourages; s.51 should be repealed.

⁷ (That case was concluded 20 September 2022; shortly before the time of this writing.)



CALL FOR A WEBMASTER

Dear Friends:

As you know, the Chemistry and the Law Division (CHAL), which has a membership of nearly 1,500 professionals, has been serving the ACS community for many decades by providing updates and guidance on laws and regulations affecting chemistry in general and the chemical professionals. Due to the increasing demand and interest in legal aspects affecting many areas of chemistry, including toxicology, chemical safety, and patent law, the Division is looking for a Webmaster who can update and monitor the Division's website so that the website serves as a vibrant and growing site for participation by all chemical professionals. For example, the Webmaster would provide guidance to the ACS members to post periodic social media updates. Although this is a voluntary position, CHAL will cover the registration fee of the Webmaster when she or he attends the ACS national meetings. If you have an interest in serving as a Webmaster, please contact the Chair of the Division, Katie Rubino by email at: Katie@caldwellip.com. We look forward to hearing from you soon.

Thank you!

This Newsletter is Published in the United States of America

Copyright © 2023

Division of Chemistry and The Law, American Chemical Society.

A primary version of this newsletter is published twice yearly as Adobe pdf prior to ACS national meetings. It is sent to CHAL members via e-mail. Copies as print-on-paper are for distribution at those meetings, and are for U.S. Postal Service mailing to CHAL members who so request. Opinions expressed are those of the authors and not necessarily of CHAL or ACS. While great effort is made for accuracy, factual errors are possible; CHAL and ACS bear no liability for such errors, and CHAL invites correction for future publication.

References, including internet sites, cited as bibliography or for general interest, are intended for readers' convenience only, and are not endorsed as to opinions or for detailed accuracy or timeliness, which are the responsibilities of the authors and publishers of those references. Internet site citations were thought to be timely within a few weeks before this newsletter would be fixed for publication; however, some may have become stale. Mention of publications, products, or services is intended for readers' convenience only and not as commercial endorsement. Discussion of legal issues is for information and educational purposes and is not legal advice; legal advice should be sought from licensed lawyers formally consulted for that purpose. Readers' comments are welcome and future articles from them are invited -- especially to broaden the range of topics and viewpoints -- address all inquiries to chal@chemistryandthelaw.org.



CHAL'S 2023 EXECUTIVE COMMITTEE

Katherine Ann Rubino, Chair Caldwell Intellectual Property Law 200 Clarendon Street, 59th floor Boston, MA 02116 Phone: (857) 626-7061 katie@caldwellip.com

Xavier Pillai, J.D., Ph.D., Past-Chair, Alternate Councilor Leydig, Voit & Mayer, Ltd. Two Prudential Plaza, Suite 4900 Chicago, IL 60601 Phone: (312) 616-5727 xpillai@leydig.com

Richard Bone, Chair-Elect Genentech, Inc. 1 DNA Way South San Francisco, CA 94080 Phone: (650) 866-6296 bone.richard@gene.com

Jonathan L. Kennedy, *Treasurer* McKee, Voorhees & Sease, PLC 801 Grand Avenue, Suite 3200 Des Moines, IA 50309 Phone: (515) 288-3667 jonathan.kennedy@ipmvs.com

Ed Mantilla,

Secretary and Communications Chair
Thermo Fisher Scientific
168 3rd Avenue
Waltham, MA 02451
Phone: (978) 215-1322
edgardo.mantilla@thermofisher.com

Dr. James Carver, Councilor
The Baringer Law Firm LLC
201 St. Charles Street
Baton Rouge, LA 70802
Phone: (225) 636-2642
ACS-Carver@thecarverlawfirm.com

Dr. Brian Meadows, *Councilor*Ballard Spahr
999 Peachtree St NE, Suite 1600
Atlanta, GA 30309
Phone: (678) 420-9414
meadowsb@ballardspahr.com

Justin J. Hasford, Archivist, Alternate Councilor Finnegan Henderson Farabow, Garrett & Dunner, LLP 901 New York Avenue, NW Washington, DC 20001 Phone: (202) 408-4000 justin.hasford@finnegan.com

Matthew J. Hlinka, Program Chair Finnegan Henderson Farabow, Garrett & Dunner, LLP 901 New York Avenue, NW Washington, DC 20001 Phone: (202) 408-4333 matthew.hlinka@finnegan.com