No. 22-899

IN THE

Supreme Court of the United States

JASON SMITH,

Petitioner,

v.

STATE OF ARIZONA,

Respondent.

On Writ of Certiorari to the Court of Appeals of Arizona, Division One

BRIEF OF *AMICI CURIAE* AMERICAN BOARD OF FORENSIC TOXICOLOGY, AMERICAN SOCIETY OF CRIME LABORATORY DIRECTORS, ASSOCIATION OF FORENSIC QUALITY ASSURANCE MANAGERS, CENTER FOR FORENSIC SCIENCE RESEARCH AND EDUCATION, INTERNATIONAL ASSOCIATION OF CORONERS AND MEDICAL EXAMINERS, NATIONAL ASSOCIATION OF MEDICAL EXAMINERS, AND SOCIETY OF FORENSIC TOXICOLOGISTS IN SUPPORT OF RESPONDENT

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae are a coalition of established scientific and forensic organizations dedicated to quality, reliability, and longevity in forensic science and its role in the judicial process. The members, fellows, and diplomates of these organizations have spent their careers improving the standards surrounding forensic science to increase the reliability and accuracy of forensic testing. *Amici's* particular interests here are two-fold: to ensure that this Court understands the rigorous standards to which the forensic science community *Amici* represent holds themselves, and to contextualize for this Court the broad sweeping impact Petitioner's proposed rule prohibiting the use of testifying witnesses will have on these disciplines.

Amici include:

American Board of Forensic Toxicology (ABFT) provides a certification program in forensic toxicology for forensic toxicology professionals and is not a membership organization. ABFT's purpose is to establish and enhance voluntary standards for the practice of forensic toxicology and for the examination and certification of scientists and accreditation of laboratories providing forensic toxicology services.

American Society of Crime Laboratory Directors (ASCLD) is an international nonprofit professional society of crime laboratory directors and forensic science managers. It presently has over 700 members

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[1] Under Sup. Ct. R. 37.6, no counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund its preparation or submission. No person other than Amici and their counsel made a monetary contribution to the preparation or submission of this brief.

representing over 400 public and private organizations dedicated to excellence in forensic science. The organization fosters professional interests, assists in the development of laboratory management principles and techniques, and promotes, encourages, and maintains the highest standards of practice and ethical conduct.

Association of Forensic Quality Assurance Managers (AFQAM) promotes standardized practices and professionalism in quality assurance management for the forensic community to provide the criminal justice system with the highest quality laboratory results and service. AFQAM has approximately 300 members, representing local, county, state, international, and federal law enforcement laboratories and other organizations dedicated to advancing forensic quality assurance.

Center for Forensic Science Research and Education (CFSRE) is a non-profit foundation dedicated to research, continuing professional education, and outreach in the forensic sciences. CFSRE conducts research, development, and new technology assessment and delivers education and training programs for the international forensic science community.

International Association of Coroners and Medical Examiners (IACME) focuses on medicolegal death investigation. It presents educational programs designed to assist coroners, medical examiners, and other forensic specialists in performing their duties and responsibilities. IACME currently has over 2,754 members from approximately forty different countries.

National Association of Medical Examiners (NAME) is a professional organization for medical examiners, forensic pathologists, and medicolegal

affiliates and administrators. It is committed to providing leadership and advocacy for best practices and excellence in forensic pathology and death investigation, developing and promulgating forensic autopsy standards, and enhancing public health through thorough, accurate death investigations and certification.

Society of Forensic Toxicologists (SOFT) is a professional scientific community of approximately 1,500 members committed to the advancement of forensic toxicology through collaboration, education, professional development, and promotion of research in the interest of justice and public health. Its affiliated Scientific Working Group in Forensic Toxicology investigated, analyzed, developed, and disseminated consensus standards for best scientific practices in forensic toxicology.

SUMMARY OF THE ARGUMENT

Petitioner and his *amici* invite this Court to adopt a rule that prohibits the use of a testifying witness—that is, a witness who did not prepare the original report. While Petitioner clothes his argument in the Confrontation Clause, his true concern is reliability. Absent the ability to cross examine a witness with personal knowledge, he argues, the opinion is unreliable and shields misconduct and other potential problems from a jury's consideration.

His proposal is so broad sweeping it would touch *any* scientific discipline. Petitioner's proposed rule presents this Court with a sea change in both the scope of the Confrontation Clause and application of the Federal Rules of Evidence. This Court has already questioned the wisdom and viability of this type of rule. *See Williams v. Illinois*, 567 U.S. 50, 89 (2012) (Breyer, J., concurring) (describing such rule as lacking a "logical stopping place").

Petitioner's arguments assume that forensic science is inherently unreliable and that, absent a witness with personal knowledge, fraud and incompetence will be free flowing. These are not valid assumptions for the reasons shown below. Nor are they true Confrontation Clause concerns. "The rules of evidence, not the Confrontation Clause, are designed primarily to police reliability; the purpose of the Confrontation Clause is to determine whether statements are testimonial and therefore require confrontation." *Bullcoming v. New Mexico*, 564 U.S. 647, 669 n.1 (2011) (Sotomayor, J., concurring in part). So long as a testifying witness has reached an independent opinion—meaning she has undertaken her *own* review and analysis of the underlying data and reports to arrive at her *own* conclusion—the defendant's right to confront that expert as to the opinion's reliability and veracity remains unharmed.

ARGUMENT

I. FORENSIC CRIME LABORATORIES AND ORGANIZATIONS UTILIZE STRINGENT PROCESSES TO ENSURE RELIABILITY AND MEMORIALIZATION OF DATA.

Petitioner challenges the reliability of a testifying witness on the assumption that the testifying witness's lack of personal knowledge is fatal to the opinion's reliability. The circumstances under which the forensic scientific community practice today demonstrate the contrary, given its use of highly credentialed personnel, national and international accreditation processes, stringent quality assurance programs, and data management systems.

A. Personnel in forensic crime laboratories and organizations are highly qualified.

The educational requirements to be hired into a forensic scientist position are rigorous. There are educational requirements for disciplines such as forensic DNA, toxicology, and chemistry. *See, e.g.*, 37 Tex. Admin. Code Ann. §§ 651.201–222 (providing license requirements for forensic analysts and technicians). Most laboratories require discipline-specific coursework within a four-year natural science degree. *See, e.g*., Md. Code Regs. 10.10.09.01–.05. Selected candidates may also undergo a variety of testing prior to beginning employment, including background investigations, drug testing, psychological evaluation, and polygraph examination (on an agency-specific basis). *See, e.g.*, Md. Code Regs. 10.10.09.01–.03; 37 Tex. Admin. Code Ann. § 651.222.

Accredited certification boards require a combination of educational training and experience to meet the eligibility requirements for admission to the certification examination. *See* Certification, ABFT, https://www.abft.org/certification/ (last visited Dec. 19, 2023). Applicants must meet high character requirements, be actively engaged in the practice of forensic toxicology, and pass a certification exam. ABFT provides certification at the Fellow, Diplomate, and Analyst levels for toxicologists with varying degrees of forensic experience. *See* Certification Categories, ABFT, https://www.abft.org/certification-categories/ (last visited Dec. 19, 2023).

Separately, forensic pathologists are fully trained and licensed physicians who completed additional residencies and fellowships in clinical and anatomic pathology. They then complete an additional fellowship in the unique subspecialty of forensic pathology.

The American Board of Pathology requires a medical school diploma, medical licensure, and completion of a minimum of thirty autopsies to qualify for the Board certification exam. *See* Requirements for Certification, American Board of Pathology, https://abpath.org/requirements/ (last visited Dec. 19, 2023). A pathologist must sit for a subspecialty certification exam in forensic pathology in order to become a Board-Certified Forensic Pathologist. *See* Forensic Pathology Exam Description, American Board of Pathology, https://abpath.org/subspecialty-certification/forensic-pathology/ (last visited Dec. 19, 2023).

The rigorous vetting a medicolegal death investigator, forensic scientist, pathologist, or analyst undergoes does not stop upon hiring or Board certification. Accredited laboratories, coroners, and medical examiners must ensure that each individual meets annual continuing education requirements.

B. Many forensic crime laboratories and organizations are nationally or internationally accredited.

Accreditation of forensic science laboratories and organizations adds to the reliability and trustworthiness of forensic science. Accreditation demonstrates that these organizations conduct their activities in conformance with a specific set of recognized standards.

The American National Standards Institute (ANSI) National Accreditation Board (ANAB) is an accreditation organization for many disciplines, including a specific forensic science accreditation program for organizations. *See generally Accreditation Requirements for Forensic Testing and Calibration*, ANAB, (Doc. No. 3125, 2023), https://anab.qualtraxcloud.com/ShowDocument.aspx?ID=12371. ANAB accredited forensic

laboratories are required to offer training in the legal standards concerning expert testimony and ethical conduct. *Id*. at 6.2.2.2. These courses may, in some laboratories and organizations, cover the Federal Rules of Evidence, *Brady v. Maryland*, 373 U.S. 83 (1963), and *Giglio v. United States*, 405 U.S. 150 (1972).

Internationally accredited laboratories participate annually in accreditation activities under standards established by the International Organization for Standardization (ISO). ISO is an independent, non-governmental international organization with a membership of 169 national standards bodies. *See* About Us, ISO, https://www.iso.org/about-us.html (last visited Dec. 19, 2023). Its ISO/ IEC 17025 standard provides the "[g]eneral requirements for the competence of testing and calibration laboratories" and "enables laboratories to demonstrate they operate competently and generate valid results, thereby promoting confidence in their work both nationally and around the world." *See* ISO/ IEC 17025, ISO, https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html (last visited Dec. 19, 2023); *see also* ISO/IEC 17025 – *General requirements for the competence of testing and calibration laboratories*, ISO, https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100424.pdf (describing the applicable standard).

In 2017, this standard was revised to specifically require laboratories to consider and perform an assessment of the risk to the result, their customers, and themselves in how they perform their activities. A part of that assessment is to assess the risk that the result is incorrect. *See* ISO/IEC 17025, ISO, https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html. In the United States, administration of

ISO/IEC 17025 to forensic laboratories and organizations is done largely by ANAB. That process requires several steps, including document review, accreditation assessment, corrective action, an accreditation decision, and surveillance and reassessment.

Other international standards exist. These include the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee. *See* Principles for the Development of International Standards, Guides and Recommendations, World Trade Organization, https://www.wto.org/english/tratop_e/tbt_e/principles_standards_tbt_e.htm (last visited Dec. 19, 2023). They also include standards promulgated by the ASTM Committee on Forensic Sciences and the Academy Standards Board (ASB). ASTM International, https://www.astm.org/ (last visited Dec. 19, 2023); Academy Standards Board, https://www.aafs.org/academy-standards-board (last visited Dec. 19, 2023).

Similarly, an individual may go through an analogous certification process to be recognized as certified by an accrediting body based on their training, education, a competency exam, and a record of continuing professional education. The Forensic Specialties Accreditation Board (FSAB) presently recognizes ten certifying bodies, including *Amici* ABFT. *See* FSAB Conformity Assessment Bodies, FSAB, https://thefsab.org/cabs/ (last visited Dec. 19, 2023).

In recent decades, there has also been a drive to standardize forensic science in the United States. In 2000, Congress passed a law to improve the quality and credibility of and provide funding opportunities for criminal justice forensic science services. *See* 34 U.S.C. §§ 10561–66. In 2014, the National Institute of

Standards and Technology (NIST) in the Department of Commerce and the Department of Justice (DOJ) created the Organization of Scientific Area Committees (OSAC) for Forensic Science. The OSAC was established as a response to the NAS Report, on which several of Petitioner's *amici* rely. Memo. of Understanding (Aug. 2015), https://www.justice.gov/archives/ncfs/file/761051/download#:~:text=The%20purpose%20of%20this%20Memorandum,guidance%20and%20policy%20recommendations%20.

The OSAC brought together subject matter experts to collaborate on determining best practices and develop consensus standards. Its mission is to support the development of science-based standards, foster the use of these standards throughout the forensic science community, and have the legal system accept the approved standards. More than 550 forensic science practitioners and other experts representing all levels of the government, academia, and industry are represented on its committees. The OSAC's Quality, Legal Factors, and Human Factors Committees vet every standard proposed, and provide overview by prosecutors, defense attorneys, academic scientists, researchers, quality experts and statisticians. This "strengthens the nation's use of forensic science by facilitating the development and promoting the use of high-quality, technically sound standards." About OSAC, NIST, https://www.nist.gov/organization-scientific-area-committees-forensic-science (last visited Dec. 19, 2023). NIST's OSAC registry contains hundreds of standardized procedures, guidelines, and recommendations for the various types of forensic testing. *See* OSAC Registry, NIST, https://www.nist.gov/organization-scientific-area-committees-forensic-science/osac-registry (last visited Dec. 19, 2023). These standards recognize that from "the crime scene to the courtroom, having valid and reliable forensic science is essential" and that standards "help to

enhance the validity and credibility of results[.]" OSAC Registry Implementation, NIST, https://www.nist.gov/organization-scientific-area-committees-forensic-science/osac-registry-implementation (last visited Dec. 19, 2023). The subject matter of these standards covers nearly all forensic science disciplines and they help to inform individual laboratories and organizations in developing standard operating procedures. *Id*.

For example, under the "Seized Drugs" discipline, OSAC provides ASTM E2548: Standard Guide for Sampling Seized Drugs for Qualitative and Quantitative Analysis (last updated May 12, 2022), https://compass.astm.org/document/?contentCode=ASTM%7CE2548-16%7Cen-US&page=1. That standard "covers minimum considerations" for conducting this analysis, the purpose of which is to "answer relevant questions," including whether a substance contains a given drug at a given level of confidence. *Id*. at 1. It also provides an exemplar sampling strategy, scheme, and plan, with decision flowcharts. *Id*. at 1–3. Notably, the standard is "subject to revision at any time by the responsible technical committee and must be reviewed every five years and if not revised, either reapproved or withdrawn"—ensuring its timeliness and accuracy. *Id*. at 4. OSAC also provides methods and suggestions for implementing its strategies. Voluntary implementation of the OSAC Registry standards by forensic science service providers signals a healthy and forward-leaning forensic science enterprise at a national level—both to stakeholders and legislative bodies. This independent addition of standards into a quality management system also indicates the service providers embrace continuous quality improvement.

Many states also have their own forensic science oversight and state commissions that implement the

ANAB, ABFT, and other quality assurance standards described below. Jeri D. Ropero-Miller & Nicole Jones, *Forensic Science State Commissions and Oversight Bodies–A 2022 Update*, RTI International (Aug. 2022), at 36-54, https://forensiccoe.org/private/654825e11c28b. This "state and local engagement is required because over 93% of forensic laboratory services are required and provided by state and local laboratories." *Id*. at 11. Some states, like Texas and New York, also utilize criminal procedure rules or regulations to compel disclosure of exculpatory and other information. *See* Tex. Code Crim. Proc. Ann. art. 39.14; Tex. Forensic Sci. Comm'n Regs., 2013 SB-1238, 2015 SB-1287; *see also* N.Y. Crim. Proc. Law § 245.20.

C. Forensic laboratories and organizations have active quality assurance departments and stringent quality assurance standards.

Forensic science laboratories and organizations typically operate under a quality management system (QMS). A QMS is a set of policies, processes, and procedures required for planning and execution of the core areas of an organization. *See* ISO 9001 – *Quality management systems*, ISO, https://www.iso.org/standards/popular/iso-9000-family (summarizing standards). A QMS helps coordinate and direct a laboratory's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.

Most laboratories and organizations have an individual or department that is responsible for overseeing the QMS. These responsibilities include ensuring compliance with internal, external, and stakeholder regulations and policies; ensuring all accreditation requirements are satisfied; identifying and mitigating

risks; overseeing personnel training; reviewing quality control measures; identifying and remediating nonconformances; and overseeing annual internal audits. All quality assurance measures are constantly reviewed, with a goal of continuous quality improvement.

The QMS typically includes a variety of quality measures that ensure results are valid and reliable. For instrumentation and equipment, this includes validation of equipment and methods, equipment calibration, intermediate checks, and other quality control measures. The appropriate validation or performance verifications must be completed and reviewed prior to the instrument being used in casework. Calibrations and intermediate checks occur throughout the instrument's life and are documented, demonstrating that the instrument is meeting the required specifications. To be permitted to handle evidence and casework, the analyst must pass competency training and an authorization process. That testing continues even after the analyst passes through regular competency testing.

QMS also use processes to detect anomalies or nonconformances. This process includes identifying the nonconformance, evaluating it, performing a root cause analysis, and implementing a corrective action plan as necessary to prevent it from reoccurring. Adjacent to this process is a proactive improvement known as preventive action. Combined, these two processes are used to continually improve the laboratory's methods and activities.

D. Forensic crime laboratories and organizations use Laboratory Information Management Systems to secure data.

A Laboratory Information Management System (LIMS) is an integrated part of many forensic

laboratories and organizations. In 2020, the National Institute of Justice's Forensic Technology Center of Excellence conducted a landscape study of LIMS, including the benefits of having one. Katherine Bollinger, et al., *A Landscape Study of Laboratory Information Management Systems (LIMS) for Forensic Crime Laboratories*, Forensic Technology Center of Excellence (Aug. 2020), https://forensiccoe.org/private/6548191d05b7d. The study's findings are instructive.

A LIMS is usually a software based, information management system "that collects, creates, and stores all data related to forensic examinations in a crime laboratory." *Id*. at 4. It is "critical" in managing evidence processing in forensic laboratories and is used to "ensure that evidence is tracked, assessed, and documented accurately and transparently." *Id*. Information stored in a LIMS is discoverable and is typically provided as part of a standard disclosure.

At the case level, a LIMS collects information so that the laboratory can "easily track the status of an item of evidence." *Id*. All LIMS offer a standard set of basic functions to document case-related information; manage laboratory processes and resources; enable data integrity and security; and generate internal and external reports. *Id*. Advanced features—such as streamlined communication among agencies, laboratories, and courts—are also available. *Id*. Each of the four basic LIMS functions enhance a forensic laboratory's reliability.

The case-related management function collects, creates, and stores the data concerning a specific case "from the submission of an item of evidence to reporting results." *Id*. at 5. This data includes, but is not limited to, "information for pieces of evidence, contextual and investigative information from the

submitting agency, prescribed analytical methods, analysis preparation procedures, analyst notes, test results, quality control processes, records of evidence storage, retention, and consumption, and any relevant reports generated from the examinations." *Id*. In short, it is comprehensive—operating from the basic premise that if it is not documented it did not happen.

The LIMS also documents chain of custody from the time an item is entered into the system, through analysis, and finally until transfer of evidence is made back to the agency or court. *Id*. Bar codes are typically used to facilitate this process. Use of a LIMS assists a laboratory in achieving and maintaining compliance with accreditation standards and storing and making accessible important quality assurance (QA) documentation. *Id*. And "LIMS can be used to generate discovery material and associate written procedures with casework, so that relevant case information is easily available to criminal justice stakeholders." *Id*.

The laboratory management function assists in managing processes and resources, enabling managers to view the entire crime laboratory's caseload or reporting turnaround time. *Id*. This feature also helps with QA processes, assisting in creating a "chain of technical and administrative review processes" and "streamline the peer-review process through an automated request system that automatically sends reports to the next reviewer." *Id*. This ensures that these processes are not overlooked or inadvertently skipped.

The data integrity and security function "documents *all* interactions with the evidence—who has analyzed the evidence, what updates have been made to the request for service, such as data reviews, interpretations, and conflict resolutions." *Id*. (emphasis added).

This protects the data's integrity and validity because "LIMS protects the raw results from alteration after an analysis has been made, documents the analysis, and locks authorized data fields." *Id*. Audit trails are generated as to who accessed the evidence, when it was placed in or removed from inventory, and when it was returned to storage. *Id*. A LIMS also tracks who accesses the data about the case and who makes any changes to the records and also permits a laboratory to restrict access to certain portions of the system, depending on the user's operational needs. *Id*. at 5–6. "The result is greater confidence in the quality and accuracy of data in a court of law, and a reduction in ability to introduce data entry errors." *Id*. at 6.

Finally, the reporting function enables data aggregation for reporting to key stakeholders. Reports can be generated on case or aggregate level and are often used to assess a laboratory's efficiency or to justify additional funding. *Id*.

II. EACH STEP IN THE FORENSIC ANALYSIS PROCESS IS MADE AND RECORDED UNDER THESE STRINGENT AND CONTROLLED PROCESSES.

The disciplines *Amici* represent diligently use and rely on these stringent and controlled processes in their daily workflow and analysis.

A. Forensic toxicology example.

Forensic toxicology encompasses the measurement of alcohol, drugs, and other toxic substances in biological specimens and interpretation of such results in a medicolegal context. A typical forensic toxicology laboratory performs forensic examinations on biological specimens using a segmented workflow with trained

and qualified individuals completing each step in a manner analogous to forensic drug chemistry analysis. While subject to some variation, the workflow described below is representative of the process employed in forensic laboratories and organizations. *See, e.g.,* Standard Practices for Method Validation in Forensic Toxicology, Standard 036, ANSI/ASB (2019), https://www.aafs.org/sites/default/files/media/documents/036_Std_e1.pdf (last visited Dec. 19, 2023); Standard for a Quality Control Program in Forensic Toxicology Laboratories, Standard 054, ANSI/ASB (2021), https://www.aafs.org/sites/default/files/media/documents/054_Std_e1.pdf (last visited Dec. 19, 2023); Standard for the Minimum Content Requirements of Forensic Toxicology Procedures, Standard 152, ANSI/ASB (2021), https://www.aafs.org/sites/default/files/media/documents/152_Std_e1.pdf; ANSI/ASTM E3255-21, E2448-16, and E2329-17.

Accessioning, or log-in, occurs first. An individual tasked with this step first documents the specimen's chain of custody. A case is opened and verified in the LIMS, including identifiers and notes, and the case is assigned a unique identifier in the system. The parent sample (the original sample provided for testing) is assigned a unique identifier and stored in a secure temperature-controlled location. From this point forward, all evidence is electronically tracked using the unique identifier. An analysis request is also entered in the LIMS, specifying which tests are requested.

Aliquoting, or sampling, occurs next. Frequently, a different individual than the one who performed the accessioning process completes this step. This individual—the "aliquoter"—retrieves the sample and removes a portion of the sample from the parent tube for testing. The sample is placed into a new, uniquely identified test tube so that all of the required follow up

tests may be performed. An individual case may require multiple tests using different methods for different drugs, so the process described below may be repeated in several parallel rounds for each drug in the sample, eventually involving multiple, sometimes dozens of people; each specimen sampled for each test is given a unique number for tracking to avoid sample mix-ups.

Analysis of the sample occurs next. A forensic scientist assembles an analytical batch consisting of samples, calibrators, and quality controls (positive and negative). Calibrators are the scale against which the quantities of drugs in suspect samples are measured. Quality controls are samples independently prepared with known amounts of the target drugs and tested by the same procedures to ensure the testing methodology is producing accurate results. This information is also recorded in the LIMS. A scientist then performs a chemical extraction and analysis of the sample, calibrators, and quality controls according to the applicable standard operating procedure (SOP). The SOP is annually reviewed and approved by the laboratory director or a designee. A second individual, often a different scientist, then places the sample onto an instrument for testing by gas chromatography, gas chromatography mass spectrometry, or liquid chromatography tandem mass spectrometry. That instrument itself also generates an electronic record of the sequence of testing, which is also documented in the LIMS. Each of these steps may be performed by the same or by a series of different scientists, depending on the laboratory's resources and workload.

Once the testing is complete, the data analysis or calculation step occurs. The "calculator" or "first reviewer"—who may be a different individual than the

first scientist—retrieves the data from the testing instrument. That scientist first reviews the raw data to ensure quality control compliance. The raw data must demonstrate that the quality control parameters for the specific SOP are met. If they are, the results may be electronically transferred from the instrument to the LIMS and the sample is subjected to a second review. If the quality control parameters are not met, the reason is investigated and unless it can be remediated with documentation, the test is cancelled and the result not reported. The process would begin again with a fresh aliquot. Any records of remediation are also noted in the LIMS or elsewhere. If the data are acceptable and within allowable limits, the results are finalized in the LIMS.

A senior scientist or a Board-Certified toxicologist then prepares the toxicology report. This individual becomes the certifying scientist and is assigned to be the scientist of record for the case and will sign the report. This certifying scientist independently reviews *all* the information collected in the LIMS, for each step, in each test, for each drug as described above—including quality control, SOP, and instrument specific data. This certifying scientist is the only individual to review this information from start to finish. This scientist reserves the discretion to accept or reject the result, order additional testing, retesting, or other remediation based on their review. All the associated technical records generated by the certifying scientist are reviewed independently by a different qualified certifying scientist before reporting. *See* Forensic Toxicology Laboratory Accreditation Checklist, ABFT (July 1, 2023), at 26, https://www.abft.org/wp-content/uploads/2023/04/ABFT_LAP-Checklist_2023-v.Jan-31.pdf (requiring that technical review of all analytical data must be undertaken by at least one qualified

person other than the analyst). Once satisfied, the certifying scientist will make findings and conclusions in a report that reflects their assessment of all laboratory analyses pertinent to the case and sign the report. By doing so, this scientist becomes the toxicologist of record for the case, taking ownership of the accuracy and completeness of the testing.

Furthermore, all the data relied on by the certifying scientist to complete the report is available and provided to the defense in discovery to allow independent assessment of the certifying scientist's process and conclusions.

B. Forensic pathology example.

Forensic pathology is the practice of medicine and a subspecialty focused on determining the cause and manner of death, especially in cases that are sudden, unexpected, traumatic, causes that may have legal significance. The procedures to determine the cause and manner of death in forensic pathology are rigorous and standardized. *See* Garry F. Peterson & Steven C. Clark, *Forensic Autopsy Performance Standards*, National Association of Medical Examiners (Oct. 2005, amended Oct. 2022, Oct. 2023), https://name.memberclicks.net/assets/docs/2020%20NAME%20Forensic%20Autopsy%20Standards%2010-17-2023.pdf; Medical Examiners' and Coroners' Handbook on Death Registration and Fetal Death Reporting, Centers for Disease Control and Prevention (2003), https://www.cdc.gov/nchs/data/misc/hb_me.pdf; Physicians' Handbook on Medical Certification of Death, Centers for Disease Control and Prevention (2003), https://www.cdc.gov/nchs/data/misc/hb_cod.pdf.

During a forensic autopsy, the forensic pathologist follows a set of standardized procedures. *See generally*

Peterson & Clark. These procedures include a thorough review of the circumstances of the death, an investigation of the scene, the decedent's medical history, and the decedent's social history, in addition to an external examination, an internal examination, and ancillary testing such as toxicology, histology, and radiology. *Id.* at 13, 23. The process is thorough and systematic and is exactly the same process clinicians use in other areas of medicine. Collectively, these physicians obtain a clinical history, physically examine a patient, order lab tests and x-rays, and report their findings and opinions. In turn, other physicians can read and interpret these documents and findings as part of the subsequent report. Medical examiners and coroners have a duty to maintain these records just as a hospital does with their patient records.

A forensic autopsy is documented through notes, diagrams, radiographs, and photographs, which become part of a comprehensive postmortem examination report detailing a complete record of findings. *Id.* at 7, 10, 16, 24. Depending upon the surrounding circumstances (suspected sexual assault or firearm injury, for example), specific, additional external examination procedures also apply. *Id*. at 15–17.

The reports must be readable, descriptive of objective findings, and include interpretations and opinions. *Id*. at 24. The report typically has two parts: (1) the objective forensic autopsy with its findings, including toxicological tests, special tests, and microscopic examination; and (2) the interpretations of the forensic pathologist. *Id*. Specifically the report includes the objective forensic autopsy with its findings, including anatomic findings of disease and injury, toxicological tests, special tests, and microscopic examination; interpretations of the forensic pathologist (e.g., the cause of

death); a written narrative of the postmortem examination; the date, place, and time of the examination; the deceased's name and case number; external and internal examination observations; description of external and internal injuries; descriptions of findings in sufficient detail to support diagnoses, opinions, and conclusions; a list of the diagnoses and interpretations; a cause of death; the name and title of each forensic pathologist(s); and the signature and date when postmortem examination report was completed. *Id*.

III. A TESTIFYING WITNESS'S OPINION IS BASED ON INDEPENDENT REVIEW OF THE DATA AND REPORTS GENERATED DURING THESE RIGOROUSLY DOCUMENTED STEPS.

Petitioner's proposed rule assumes that having the original scientist will provide a more meaningful opportunity for confrontation than the testifying witness provides. This is simply not true in either forensic toxicology, chemistry, pathology, or other forensic disciplines.

Importantly, in the event the original certifying scientist becomes unavailable or cannot testify, the documented process allows the entire review process to be repeated by another scientist who then serves as the testifying witness. The testifying witness will draw an independent conclusion, regardless of the original conclusions, about the completeness and accuracy of the test and reflect that in their own opinions, often issuing a new, signed report. It is then *that* report that the defendant confronts at trial.

Petitioner's assumption that having each participant in the forensic testing process—from accessioning to final report—will produce individuals with greater personal knowledge, is incorrect. The segmented

workflow described above means that each participant in the process is unlikely to have any personal knowledge that would allow for meaningful cross examination. The sheer workload demands on a forensic laboratory means the volume of specimens make the memory of a specific case unremarkable. The fact that the original scientist is testing thousands, sometimes tens of thousands, of cases every year means there is no independent recollection of each analysis. Thus, the original scientist would rely on these same records to refresh their recollection were they to testify. And to the extent there are any anomalies or issues in the testing process, they are recorded in the LIMS contemporaneously, making the system, rather than the scientist, the more reliable witness.

Further, a testifying witness is in no different a position than the signing certifying scientist. In order to offer an *independent* opinion, the testifying witness cannot simply testify as to what the original report concluded. The testifying witness must instead analyze the same information from the LIMS to reach their own opinion. This means that a testifying witness is engaging in the same analytical process undertaken to arrive at the original conclusion. The testifying witness must still verify that the casework, quality control, and instrument data supports the conclusion. The fact alone that the testifying witness has the benefit of the original certifying scientist's report does not mean that the process the testifying witness undertakes is not reliable. To the contrary, it is no different than any other peer review process undertaken in any other scientific discipline. In some instances, the second, thorough review a testifying witness completes may yield a different conclusion than the original report, working to a defendant's benefit.

Petitioner's assumption is further disproven in forensic pathology. Where the autopsy standards are followed, the testifying pathologist will review and analyze the same materials the original pathologist used, including the examination report, photographs, and laboratory results. The testifying pathologist uses the same standardized, medically rigorous procedures to reach a conclusion. This process mirrors the process physicians in other disciplines rely on in interpreting diagnostic tests or medical records prepared by other clinicians in their field.

In addition, months or years have typically passed between the autopsy and a criminal trial. This means the original pathologist who performed the autopsy would typically be as dependent on the notes, data, reports, and conclusions reached as the testifying pathologist. The forensic pathology discipline is predicated on standardized and rigorous procedure that enable any qualified forensic pathologist to provide accurate and reliable explanations and interpretations of autopsies, their reports, and accompanying test results. To the extent an issue exists where personal knowledge would be essential, this is an area appropriate for cross examination, not wholesale exclusion of the testifying pathologist's opinion.

While the disciplines of forensic toxicology and pathology have been described in detail due to their complexity, analogous reliable systems apply to drug chemistry and other forensic disciplines, producing equally reliable testifying witnesses.

IV. THE FEDERAL RULES OF EVIDENCE AND CROSS EXAMINATION ALLOW A CRIMINAL DEFENDANT TO CONFRONT THE TESTIFYING WITNESS'S OPINION.

The Confrontation Clause of the Sixth Amendment provides that "[i]n all criminal prosecutions, the accused shall enjoy the right * * * to be confronted with the witnesses against him." U.S. Const. amend. VI. This Court has barred an expert from testifying only when the expert offering the opinion does not testify. *See*, *e.g.*, *Crawford v. Washington*, 541 U.S. 36, 50–55, 68 (2004) (holding that testimonial hearsay statements of a witness that does not appear at trial are inadmissible unless the witness is unavailable to testify and the defendant had a previous opportunity for cross-examination); *see also Davis v. Washington*, 547 U.S. 813, 823–25 (2006) (limiting *Crawford* to solely testimonial hearsay).

A testifying witness's independent opinion satisfies the Confrontation Clause because the evidence used against the defendant is that independent opinion, not an out-of-court report. *Accord Michigan v. Bryant*, 562 U.S. 344, 358 (2011) (holding a testimonial statement is one "procured with a primary purpose of creating an out-of-court substitute for trial testimony"). The defendant has two opportunities to confront that opinion: through a challenge made under Federal Rules of Evidence 702 and 703 and through vigorous cross examination.

It is beyond dispute that reliability is the threshold linchpin of an expert's testimony. *See* Fed. R. Evid. 702 (requiring that an expert's testimony be "the product of reliable principles and methods"). The plain language of Rules 702 and 703 prevent broad exclusion of forensic evidence simply because the testifying

expert did not collect the underlying data or because the expert reviewed and relied on another's report. The fact that an expert may base an opinion on facts or data of which the expert has been made aware, rather than personally observed, does not make the opinion unreliable. Fed. R. Evid. 703; *see also Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988) (noting the Rules' drafting history reflects a "general approach of relaxing the traditional barriers to 'opinion' testimony"). The fact that those facts and data may be inadmissible is irrelevant to the expert's ability to rely on them, so long as "experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject." Fed. R. Evid. 703. And that evidence may be disclosed to the jury if helpful in evaluating the expert's opinion where its probative value substantially outweighs any prejudicial effect. *Id*.

This Court has recognized that there are multiple safeguards under these rules to prevent abuse. *Williams*, 567 U.S. at 80–81. Among them is the ability of "trial courts [to] screen out experts who would act as mere conduits for hearsay by strictly enforcing the requirement that experts display some genuine 'scientific, technical, or other specialized knowledge [that] will help the trier of fact to understand the evidence or to determine a fact in issue.'" *Id*. at 80 (citing Fed. Rule Evid. 702(a)). In addition, "experts are generally precluded from disclosing inadmissible evidence to a jury." *Id*. at 80–81.

It is well-established that the reliability of an expert's opinion may be used as a basis for excluding it. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, this Court articulated the standard for determining the evidentiary reliability of scientific evidence. 509 U.S.

579, 590 (1993). "[I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method." *Id*. Proffered testimony must be supported by appropriate validation, meaning, an expert's testimony must pertain to "scientific knowledge" and it thus "establishes a standard of evidentiary reliability." *Id*. The "overarching subject is the scientific validity and thus the evidentiary relevance and reliability—of the principles that underlie a proposed submission. The focus * * * must be solely on principles and methodology, not on the conclusions they generate." *Id*. at 594–95.

"The objective of [*Daubert*'s gatekeeping] requirement is to ensure the reliability and relevancy of expert testimony." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999); *see also Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997) (holding that the Federal Rules of Evidence "leave in place the 'gatekeeper' role of the trial judge" in admitting scientific testimony). To fulfill that role, "the trial judge must have considerable leeway in deciding *in a particular case* how to go about determining whether particular expert testimony is reliable." *Kumho Tire,* 526 U.S. at 152 (emphasis added). This fact-intensive analysis is typically not subject to blanket resolution as a matter of law but instead reserved to a trial judge's sound discretion. *See Congress & Empire Spring Co. v. Edgar*, 99 U.S. 645, 658 (1878) ("Cases arise where it is very much a matter of discretion with the court whether to receive or exclude the evidence; but the appellate court will not reverse in such a case, unless the ruling is manifestly erroneous."); *Joiner*, 522 U.S. at 143 (observing that deference "is the hallmark of abuse-of-discretion review"); *see also Daubert*, 509 U.S. at 592–95 (identifying five factors for review).

To the extent that a defendant believes an expert's opinion concerning the forensic evidence used against him is unreliable, *Daubert* and Rule 702 provide the mechanism to make that case-specific challenge either pretrial or through voir dire at trial. To the extent that a defendant believes the prejudicial effect of an underlying report is too great to allow an expert to testify to its contents, the report may be excluded under Rule 703. And to the extent a defendant believes the lack of personal knowledge should be brought to the jury's attention, cross examination permits that line of questioning.

Given these safeguards, the fact that forensic scientific evidence is routinely admitted is not symptomatic of a problem or that admissibility is presupposed, as Petitioner's *amici* suggest. It is instead evidence that the rigorous, standards-based processes described above consistently meet the reliability requirements to be admissible at trial.

V. PETITIONER'S PROPOSED RULE HAS NO LOGICAL ENDPOINT AS TO THE NUMBER OF WITNESSES NECESSARY FOR COMPLIANCE.

Petitioner proposes that a testifying witness who does not personally collect each element of the underlying data or produce the initial analysis reaching a conclusion should be excluded. Petitioner's proposal presents unique challenges to *Amici*. This Court has recognized that abandoning the present rule, as Petitioner invites, means that there will be "no logical stopping place" to the number of witnesses that may be required for compliance. *Williams*, 567 U.S. at 89 (Breyer, J., concurring). Each person involved in each of the steps described above would be required to testify. The "highly destabilizing" consequences this

causes to *Amici* extend beyond the challenges the United States identifies for prosecutors. U.S. Br. at 29.

A. Petitioner's rule would force already over-burdened forensic laboratories and organizations to come to a near standstill.

The circumstances facing forensic toxicology laboratories and organizations are grim. "Over the past decade, forensic toxicology laboratories have experienced an accelerated increase in the demand for toxicological analyses without a corresponding growth in resources." Jeri D. Ropero-Miller, et al., *The Sentinel Role of Forensic Toxicology Laboratories to Identify and Act Upon Diverse Drug Threats by Addressing Toxicology and Economic Demands,* Forensic Science International: Synergy 5 (2022), at 1, https://www.sciencedirect.com/science/article/pii/S2589871X22000778.

Drug chemistry laboratories also often face large backlogs, prohibiting timely reporting of data. In 2019, the average drug chemistry laboratory in the United States had a backlog of 1,862 cases and it took sixty days for a case to be analyzed and results reported. Edward Sisco, *We Need Comprehensive Illicit Drug Analysis Now to Stop Overdose Deaths*, Scientific American, National Institute of Science and Technology (August 22, 2023), https://www.scientificamerican.com/article/we-need-comprehensive-illicit-drug-analysis-now-to-stop-overdose-deaths1/. The increased demand for testing may be attributed to "rapidly emerging and changing unknown substances in the drug market," legalization of cannabis and related products, and "[r]apidly expanding unknown substances of abuse[.]" Miller at 2. In fiscal year 2023, United States Custom and Border Control (CBP) seized more than 27,000 pounds of fentanyl, compared with over 14,600 pounds

in fiscal year 2022. U.S. Customs & Border Protections Monthly Update, September 2023 (Oct. 21, 2023), https://www.cbp.gov/newsroom/national-media-release/cbp-releases-september-2023-monthly-update (last visited Dec. 19, 2023). CBP's fentanyl seizures have increased more than 800% since fiscal year 2019. *Id.* Nationwide in September, seizures of other dangerous drugs—cocaine, methamphetamine, heroin, fentanyl, and marijuana—increased seven percent from the previous month. *Id*. In 2022, provisional data indicated that more than two thirds (sixty-eight percent) of the reported 107,081 drug overdose deaths in the United States involved synthetic opioids other than methadone, principally illicitly manufactured fentanyls. *See* Kariisa Mbabazi, et al., *Illicitly Manufactured Fentanyl-Involved Overdose Deaths with Detected Xylazine– United States, January 2019-June 2022*, Morbidity and Mortality Weekly Report, Centers for Disease Control and Prevention (June 30, 2023), https://www.cdc.gov/mmwr/volumes/72/wr/mm7226a4.htm. While a "seemingly invisible participant in the justice system's efforts to deal with the changing drug landscape, the forensic laboratory has been inundated with casework related to evolving drug use from drug chemistry to toxicology." Miller at 2.

As a result, resources are limited to address the concern, particularly given that most forensic laboratories are public. *Id*. As caseloads continue to expand, so too does the personnel needed to meet those demands. *Id.* at 3 and Fig. 2. And as caseloads increase, productivity decreases. *Id.* at 3 and Fig. 3.

Demand is therefore already high and resources are stretched thin, even without the additional requirements Petitioner's proposed rule would present. Petitioner's proposed rule would require that each participant in each step of the analytical process testify. This would

mean the routine loss of multiple personnel—in some instances as many as four or five scientists, and potentially many more—per trial. Similar personnel losses would likely occur in other forensic labs. Given the five-step DNA analysis process the FBI forensic lab undertakes for example, at least five personnel would be required per trial simply to testify to the underlying analysis process. U.S. Br. at 30.

Considering current judicial caseloads, the ask on laboratory personnels' time would be extreme. By way of only one example, in fiscal year 2023, there were 68,950 federal criminal defendant filings alone, of which drug offenses accounted for twenty-eight percent. Fed. Judicial Caseload Statistics, United States Courts, https://www.uscourts.gov/statistics-reports/federal-judicial-caseload-statistics-2023 (last visited Dec. 19, 2023). These laboratories simply cannot sustain both the increased workload and the near standstill in operations that Petitioner's proposed rule would create.

B. The current shortage and turnover of forensic pathologists would make compliance difficult.

Forensic pathologists face a different problem. There is an increasing shortage of forensic pathologists nationwide, as the discipline faces a significant workforce shortage. Based on a recent 2023 NAME Data Survey Committee survey, there are presently 791 full-time, practicing, Board-Certified forensic pathologists in the United States. In order to meet the actual autopsy needs in the United States, as determined by Centers for Disease Control and Prevention statistics, at least 1,550 Board-Certified, full-time forensic pathologists are required. In the National Institute of Justice's 2019 report to Congress, it was well documented that medical examiner and

coroner offices were underfunded, had high turnover, and experienced low morale. David B. Muhlhausen, *Report to Congress: Needs Assessment of Forensic Laboratories and Medical Examiner/Coroner Offices*, National Institute of Justice (2019), https://www.ojp.gov/pdffiles1/nij/253626.pdf. And that study was pre-COVID. Because of the shortage of forensic pathologists and high turnover, it is an increasingly common occurrence that the original pathologist will be available to testify. This would make compliance with Petitioner's proposed rule difficult, at bare minimum.

VI. ALLOWING A TESTIFYING WITNESS TO PRESENT AN INDEPENDENT OPINION DOES NOT OPEN THE FLOODGATES TO FABRICATED AND INCOMPETENT EVIDENCE.

Petitioner and his *amici* argue the broad reaching rule they propose is required to prevent abuse and malpractice. *Amici* acknowledge that the Confrontation Clause is intended, in part, to assure accurate forensic analysis and "weed out not only the fraudulent analyst, but the incompetent one as well." *Melendez-Diaz v. Massachusetts*, 557 U.S. 305, 319 (2009). Nothing suggests a correlation exists between a fraudulent scientist and the use of a testifying witness.

The keystone examples of wrongful conduct on which Petitioner's *amici* rely were not uncovered by cross examination during trial or a hearing. To the contrary, many of their examples demonstrate that a disreputable analyst is undeterred by cross examination.

For example, Annie Dookhan's fabrication of test results while employed at the Massachusetts Department of Public Health Drug Abuse lab was not discovered as the result of cross examination. Brittany Brady, *Chemist*

in Massachusetts drug sample case lied about degree, CNN (Sept. 26, 2012, 9:59 AM), https://www.cnn.com/2012/09/25/justice/massachusetts-chemist/index.html. She testified in court under oath on 150 occasions, including ninety-two hours in 2009 and 202 hours in 2010. Sam Kean, *Why Did Annie Dookhan Lie?*, Distillations Magazine, Science History Institute Museum and & Library (July 13, 2021), https://sciencehistory.org/stories/magazine/why-did-annie-dookhan-lie/. She consistently presented as a reliable witness. *Id.* It was in fact the rigorous processes employed by the laboratory in which she worked and her colleagues' discovery of inconsistencies between the control cards and evidence log book that uncovered the problems. *Id.*

Similarly, Sonja Farak, a former chemist at the Massachusetts State Crime Laboratory, also testified regularly in court. Transcript of Grand Jury Investigation at 78, 82, Office of the Attorney General In Re: Investigation (Sept. 16, 2015), https://www.documentcloud.org/documents/4347254-Ware-253-Farak-GJ-Transcript-9-16-15. Her fraud and narcotic use was not disclosed in the hours she spent testifying as a witness. *See id.* at 79. Her wrongdoing was instead discovered when the laboratory contacted the state police to report a discrepancy in the controlled substance inventory held in evidence. *State Crime Lab Chemist Arrested For Tampering With Evidence, Drug Possession*, CBS News Boston (Jan. 20, 2013, 10:32 AM), https://www.cbsnews.com/boston/news/state-crime-lab-chemist-arrested-for-tampering-with-evidence-drug-possession/.

The facts surrounding serologist Fred Zain's misconduct again show that cross examination bears little relationship to whether fraud or incompetence will be exposed. Paul C. Giannelli, *Scientific Fraud*, 46 Case Western Reserve Univ. Sch. of Law Scholarly

Commons 1313 (2010), https://scholarlycommons.law.case.edu/cgi/viewcontent.cgi?article=1097&context=faculty_publications. And the National College for DUI Defense's ambiguous assertion that "the incompetence in Austin" was identified only after in-court testimony is not entirely accurate. Nat'l Coll. Br. at 8. Instead, just before the analyst testified prosecutors in the case became concerned about her answers to their questions and her inability to complete an equation, preventing her testimony altogether. Andrea Ball & Tony Plohetski, *Austin DNA lab leader's work triggered alarm in sex assault case*, Austin American-Statesman (Jan. 9, 2017, 11:01 PM, last updated, Sept. 25, 2018, 10:26 AM), https://www.statesman.com/story/news/2017/01/10/austin-dna-lab-leaders-work-triggered-alarm-in-sex-assault-case/10123558007/.

The assertion that excluding testifying witnesses will eliminate or reduce misconduct in forensic laboratories is a bald conclusion without a supporting causal theory. Each of these instances instead show that it was in fact the standards and practices employed in the laboratories and by other forensic scientists that revealed the wrongful conduct. In other words, the very process Petitioner seeks to exclude and the rigorous standards, QMS programs, and ethics have helped to ensure that a defendant's confrontation right remains fully realized.

CONCLUSION

Amici urge this Court to reject Petitioner's proposed rule.

Respectfully submitted,

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