

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, INC.,

Petitioner

v.

UNITED THERAPEUTICS CORPORATION,

Patent Owner

U.S. Patent No. 10,716,793 B2

Issue Date: July 21, 2020

Title: Treprostinil Administration By Inhalation

DECLARATION OF SYLVIA HALL-ELLIS, PH.D.

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I, Sylvia D. Hall-Ellis, Ph.D., declare as follows:

I. INTRODUCTION

1. My name is Sylvia D. Hall-Ellis. I have been retained as an expert by Liquidia Technologies, Inc., who I am informed is a petitioner to this IPR proceeding (“the Petitioner”).

2. I have written this declaration at the request of the Petitioner to provide my expert opinion regarding the public availability of a number of publications, identified below. My Declaration sets forth my opinions in detail and provides the basis for my opinions regarding the public availability of these publications.

3. I reserve the right to supplement or amend my opinions, and bases for them, in response to any additional evidence, testimony, discovery, argument, and/or other additional information that may be provided to me after the date of this Declaration.

4. As of the preparation and signing of this declaration, many libraries across the nation are closed or permit only limited access due to the COVID-19 virus. However, were the libraries open, I would expect to be able to obtain paper copies of at least some of the documents in this declaration. Additionally, it is my typical practice to obtain a paper copy of each publication to further confirm my opinions that the documents were available prior to the alleged priority date of the patent at issue. I reserve the right to supplement my declaration when the libraries reopen to

provide such information.

5. I am being compensated for my time spent working on this matter at my normal consulting rate of \$300 per hour, plus reimbursement for any additional reasonable expenses. My compensation is not in any way tied to the content of this report, the substance of my opinions, or the outcome of this litigation. I have no other interests in this proceeding or with any of the parties.

6. All of the materials that I considered and relied upon are discussed explicitly in this declaration.

II. QUALIFICATIONS

7. I am currently an Adjunct Professor in the School of Information at San José State University in San José, California. I obtained a Master of Library Science from the University of North Texas in 1972 and a Ph.D. in Library Science from the University of Pittsburgh in 1985. Over the last fifty years, I have held various positions in the field of library and information resources. I was first employed as a librarian in 1966 and have been involved in the field of library sciences since, holding numerous positions.

8. I am a member of the American Library Association (ALA) and its Association for Library Collections & Technical Services (ALCTS) Division, and I served on the Committee on Cataloging: Resource and Description (which wrote the new cataloging rules) and as the chair of the Committee for Education and Training

of Catalogers and the Competencies and Education for a Career in Cataloging Interest Group. I also served as the Chair of the ALCTS Division's Task Force on Competencies and Education for a Career in Cataloging. Additionally, I have served as the Chair for the ALA Office of Diversity's Committee on Diversity, as a member of the REFORMA National Board of Directors, and as a member of the Editorial Board for the ALCTS premier cataloging journal, *Library Resources and Technical Services*. Currently I serve as a Co-Chair for the Library Research Round Table of the American Library Association.

9. I have also given over one hundred presentations in the field, including several on library cataloging systems and Machine-Readable Cataloging ("MARC") standards. My current research interests include library cataloging systems, metadata, and organization of electronic resources.

10. My full curriculum vitae is attached hereto as **Exhibit A**.

III. PRELIMINARIES

A. Scope of Declaration and Legal Standards

11. I am not an attorney and will not offer opinions on the law. I am, however, rendering my expert opinion on the authenticity of the documents referenced herein and on when and how each of these documents was disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could have

located the documents before the dates discussed below with respect to the specific documents.

12. I am informed by counsel that a printed publication qualifies as publicly accessible as of the date it was disseminated or otherwise made available such that a person interested in and ordinarily skilled in the relevant subject matter could locate it through the exercise of ordinary diligence.

13. While I understand that the determination of public accessibility under the foregoing standard rests on a case-by-case analysis of the facts particular to an individual publication, I also understand that a printed publication is rendered “publicly accessible” if it is cataloged and indexed by a library such that a person interested in the relevant subject matter could locate it (*i.e.*, I understand that cataloging and indexing by a library is sufficient, though there are other ways that a printed publication may qualify as publicly accessible). One manner of sufficient indexing is indexing according to subject matter category. I understand that the cataloging and indexing by a single library of a single instance of a particular printed publication is sufficient, even if the single library is in a foreign country. I understand that, even if access to a library is restricted, a printed publication that has been cataloged and indexed therein is publicly accessible so long as a presumption is raised that the portion of the public concerned with the relevant subject matter would know of the printed publication. I also understand that the cataloging and

indexing of information that would guide a person interested in the relevant subject matter to the printed publication, such as the cataloging and indexing of an abstract for the printed publication, is sufficient to render the printed publication publicly accessible.

14. I understand that routine business practices, such as general library cataloging and indexing practices, can be used to establish an approximate date on which a printed publication became publicly accessible.

B. Persons of Ordinary Skill in the Art

15. I am told by counsel that the subject matter of this proceeding generally relates to inhalation therapies, particularly involving the compound treprostinil, to treat patients with pulmonary hypertension.

16. I have been informed by counsel that a “person of ordinary skill in the art at the time of the inventions” is a hypothetical person who is presumed to be familiar with the relevant field and its literature at the time of the inventions. This hypothetical person is also a person of ordinary creativity, capable of understanding the scientific principles applicable to the pertinent field.

17. I am told by counsel that the subject matter covers two multiple disciplines. I understand that, with respect to the method of treating pulmonary hypertension, a person of ordinary skill in this subject matter or art would typically be someone with a medical degree with a specialty in pulmonology or cardiology,

plus at least two years of experience treating patients with pulmonary hypertension as an attending, including with inhaled therapies, or equivalent. I also understand that, with respect to inhaled formulations used in the method to treat pulmonary hypertension, a person of ordinary skill in this subject matter or art would typically be someone with a Ph.D. in pharmaceutical science or a related discipline like chemistry or medicinal chemistry, plus two years of experience in pharmaceutical formulations, including inhaled products, or equivalent (*e.g.*, a masters degree in the same fields, plus 5 years of experience). I have been further informed by counsel that a person of ordinary skill in the art would have been familiar with and able to understand the information known in the art relating to these fields, including the publications discussed in this declaration.

C. Use of Authoritative Databases

18. In preparing this report, I used authoritative databases, such as the OCLC bibliographic database, the Library of Congress Online Catalog, *ResearchGate*, and *Semantic Scholar*, to confirm citation details of the publication discussed.

19. *Indexing*. A researcher may discover material relevant to his or her topic in a variety of ways. One common means of discovery is to search for relevant information in an index of periodical and other publications. Having found relevant material, the researcher will then normally obtain it online, look for it in libraries, or

purchase it from the publisher, a bookstore, a document delivery service, or other provider. Sometimes, the date of a document's public accessibility will involve both indexing and library date information.

20. Indexing services use a wide variety of controlled vocabularies to provide subject access and other means of discovering the content of documents. The formats in which these access terms are presented vary from service to service.

21. Online indexing services and digital repositories commonly provide bibliographic information, abstracts, and full-text copies of the indexed publications, along with a list of the documents cited in the indexed publication. These services also often provide lists of publications that cite a given document. A citation of a document is evidence that the document was publicly available and in use by researchers no later than the publication date of the citing document.

22. *ResearchGate*.¹ A social networking site for scientists and researchers to share papers, ask and answer questions, and find collaborators, *ResearchGate* is the largest academic social network in terms of active users, although other services have more registered users, and a 2015–2016 survey suggests that almost as many academics have *Google Scholar* profiles. Features available to *ResearchGate* members include following a research interest and the work of other individual participants, a blogging feature for users to write short reviews on peer-reviewed

¹ www.researchgate.net

articles, private chat rooms for sharing data, editing documents, or discussing confidential topics, and a research-focused job board. *ResearchGate* indexes self-published information on user profiles and suggests members to connect with others who have similar interests. Member questions are fielded to others who have identified relevant expertise on their profiles.

23. *ResearchGate* restricts its user accounts to people at recognized institutions and published researchers. As of 2018, *ResearchGate* had more than 15 million users, with its largest user-bases coming from Europe and North America. Most of *ResearchGate*'s users are involved in medicine, biology, engineering, computer science, agricultural sciences, and psychology. *ResearchGate* publishes a citation impact measurement in the form of an "RG Score," which is reported to be correlated with existing citation impact measures. *ResearchGate* does not charge fees for putting content on the site and does not require peer review.

24. *Semantic Scholar*.² Developed at the Allen Institute for Artificial Intelligence and released in November 2015, *Semantic Scholar* is designed to be an AI-backed search engine for scientific journal articles which uses a combination of machine learning, natural language processing, and machine vision to add a layer of semantic analysis to the traditional methods of citation analysis, and to extract relevant figures, entities, and venues from papers. *Semantic Scholar* is designed to

² www.semanticscholar.org

highlight important, influential papers, and to identify the connections between them.

25. As of January 2018, following a 2017 project that added biomedical papers and topic summaries, the *Semantic Scholar* corpus included more than 40 million papers from computer science and biomedicine. As of August 2019, the number of included papers had grown to more than 173 million after the addition of the Microsoft Academic Graph records, already used by Lens.org.

D. Summary of Opinions

26. I am informed by counsel that the priority date for the patent at issue is May 15, 2006. As I will explain below, it is my opinion that the printed publications discussed in my Declaration were publicly accessible before the May 15, 2006 priority date.

IV. LIBRARY CATALOGING PRACTICES

A. MARC Records and OCLC

27. I am fully familiar with the library cataloging standard known as the MARC standard, which is an industry-wide standard method of storing and organizing library catalog information. MARC was first developed in the 1960's by the Library of Congress. A MARC-compatible library is one that has a catalog consisting of individual MARC records for works made available at that library.

28. Since at least the early 1970s and continuing to the present day, MARC has been the primary communications protocol for the transfer and storage of

bibliographic metadata in libraries.³ As explained by the Library of Congress:

You could devise your own method of organizing the bibliographic information, but you would be isolating your library, limiting its options, and creating much more work for yourself. Using the MARC standard prevents duplication of work and allows libraries to better share bibliographic resources. Choosing to use MARC enables libraries to acquire cataloging data that is predictable and reliable. If a library were to develop a “home-grown” system that did not use MARC records, it would not be taking advantage of an industry-wide standard whose primary purpose is to foster communication of information.

Using the MARC standard also enables libraries to make use of commercially available library automation systems to manage library operations. Many systems are available for libraries of all sizes and are designed to work with the MARC format. Systems are maintained and improved by the vendor so that libraries can benefit from the latest advances in computer technology. The MARC standard also allows libraries to replace one system with another with the assurance that their data will still be compatible.

Why Is a MARC Record Necessary? LIBRARY OF CONGRESS,
<http://www.loc.gov/marc/umb/um01to06.html#part2> (last visited December 7, 2020).

³ A complete history of the development of MARC can be found in *MARC: Its History and Implications* by Henriette D. Avram (Washington, DC: Library of Congress, 1975) and available online from the Hathi Trust (<https://babel.hathitrust.org/cgi/pt?id=mdp.39015034388556;view=1up;seq=1>; last visited December 7, 2020).

29. Thus, almost every major library in the world is MARC-compatible. *See, e.g., MARC Frequently Asked Questions (FAQ)*, LIBRARY OF CONGRESS, <https://www.loc.gov/marc/faq.html> (last visited December 7, 2020) (“MARC is the acronym for MACHine-Readable Cataloging. It defines a data format that emerged from a Library of Congress-led initiative that began nearly forty years ago. It provides the mechanism by which computers exchange, use, and interpret bibliographic information, and its data elements make up the foundation of most library catalogs used today.”). MARC is the ANSI/NISO Z39.2-1994 standard (reaffirmed in 2016) for Information Interchange Format. The full text of the standard is available from the Library of Congress at <http://www.loc.gov/marc/bibliographic/> (last visited December 7, 2020).

30. A MARC record comprises several fields, each of which contains specific data about the work. Each field is identified by a standardized, unique, three-digit code corresponding to the type of data that follow. *See, e.g.,* <http://www.loc.gov/marc/umb/um07to10.html> (last visited December 7, 2020); <http://www.loc.gov/marc/bibliographic/> (last visited December 7, 2020). For example, a work’s title is recorded in field 245, the primary author of the work is recorded in field 100, a work’s International Standard Book Number (“ISBN”) is recorded in field 020, a work’s International Standard Serial Number (“ISSN”) is recorded in field 022, and the publication date is recorded in field 260 under the

subfield “c.” *Id.*⁴ If a work is a periodical, then its publication frequency is recorded in field 310, and the publication dates (e.g., the first and last publication) are recorded in field 362, which is also referred to as the enumeration/chronology field. *See* <http://www.loc.gov/marc/bibliographic/bd3xx.html> (last visited December 7, 2020).⁵

31. The library that initially created the MARC record is reflected in field 040 in subfield “a” with that library’s unique library code. *See, e.g.,* <http://www.loc.gov/marc/umb/um07to10.html> (last visited December 7, 2020); <http://www.loc.gov/marc/bibliographic/> (last visited December 7, 2020). Once a MARC record for a particular work is originally created by one library, other libraries can use that original MARC record to then create their own MARC records for their own copies of the same work. These other libraries may modify or add to

⁴ In some MARC records, field 264 is used rather than field 260 to record publication information. *See* <http://www.loc.gov/marc/bibliographic/bd264.html> (last visited December 7, 2020) (“Information in field 264 is similar to information in field 260 (Publication, Distribution, etc. (Imprint)). Field 264 is useful for cases where the content standard or institutional policies make a distinction between functions”).

⁵ Upwards of two-thirds to three-quarters of book sales to libraries come from a jobber or wholesaler for online and print resources. These resellers make it their business to provide books to their customers as fast as possible, often providing turnaround times of only a single day after publication. Libraries purchase a significant portion of the balance of their books directly from publishers themselves, which provide delivery on a similarly expedited schedule. In general, libraries make these purchases throughout the year as the books are published and shelve the books as soon thereafter as possible in order to make the books available to their patrons. Thus, books are generally available at libraries across the country within just a few days of publication.

the original MARC record as necessary to reflect data specific to their own copies of the work. However, the library that created the original MARC record would still be reflected in these modified MARC records (corresponding to other copies of the same work at other libraries) in field 040, subfield “a”. The modifying library (or libraries) is reflected in field 040, subfield “d”. *See* <http://www.loc.gov/marc/bibliographic/bd040.html> (last visited December 7, 2020).

32. I consulted the Directory of OCLC Libraries (<http://www.oclc.org/contacts/libraries.en.html>; last visited December 7, 2020) in order to identify the institution that created or modified the MARC record. Moreover, when viewing the MARC record online via Online Computer Library Center’s (“OCLC”) bibliographic database, which I discuss further below, hovering over a library code in field 040 with the mouse reveals the full name of the library. I also used this method of “mousing over” the library codes in the OCLC database to identify the originating and modifying libraries for the MARC records discussed in this report.

33. MARC records also include one or more fields that show information regarding subject matter classification. For example, 6XX fields are termed “Subject Access Fields.” *See* <http://www.loc.gov/marc/bibliographic/bd6xx.html> (last visited March 24, 2020). Among these, for example, is the 650 field; this is the “Subject Added Entry – Topical Term” field. *See*

<http://www.loc.gov/marc/bibliographic/bd650.html> (last visited December 7, 2020). The 650 field is a “[s]ubject added entry in which the entry element is a topical term.” *Id.* These entries “are assigned to a bibliographic record to provide access according to generally accepted thesaurus-building rules (e.g., *Library of Congress Subject Headings* (LCSH), *Medical Subject Headings* (MeSH)).” *Id.*

34. Further, MARC records can include call numbers, which themselves contain a classification number. For example, a MARC record may identify a 050 field, which is the “Library of Congress Call Number.” *See* <http://www.loc.gov/marc/bibliographic/bd050.html> (last visited December 7, 2020). A defined portion of the Library of Congress Call Number is the classification number, and “source of the classification number is *Library of Congress Classification* and the *LC Classification-Additions and Changes*.” *Id.* Thus, the 050 field may be used to show information regarding subject matter classification.

35. Each item in a library has a single classification number. A library selects a classification scheme (e.g., the Library of Congress Classification scheme just described or a similar scheme such as the Dewey Decimal Classification scheme) and uses it consistently. When the Library of Congress assigns the classification number, it appears as part of the 050 field, as discussed above. For MARC records created by libraries other than the Library of Congress (e.g., a university library or a local public library), the classification number may appear in

a 09X (e.g., 090) field. See <http://www.loc.gov/marc/bibliographic/bd09x.html> (last visited December 7, 2020).

36. When a MARC-compatible library acquires a work, it creates a MARC record for its copy of the work in its computer catalog system in the ordinary course of its business. This MARC record (for the copy of a work available at the particular library) may be later accessed by researchers in a number of ways. For example, many libraries, including the Library of Congress, make their MARC records available through their website. As an example, the MARC record for the copy of *The Unlikely Spy*, by Daniel Silva,⁶ available at the Library of Congress can be viewed through the Library of Congress website, at <https://catalog.loc.gov/vwebv/staffView?searchId=20265&recPointer=1&recCount=25&bibId=2579985> (last visited December 7, 2020). One could, of course, always physically visit the library at which the work is available, and request to see that library's MARC record for the work. Moreover, members of the Online Computer Library Center ("OCLC") can access the MARC records of other member institutions through OCLC's online bibliographic database, as I explain further below.

37. The OCLC was created "to establish, maintain, and operate a

⁶ *The Unlikely Spy* is a 1996 novel written by Daniel Silva, who happens to be one of my favorite authors.

computerized library network and to promote the evolution of library use, of libraries themselves, and of librarianship, and to provide processes and products for the benefit of library users and libraries, including such objectives as increasing availability of library resources to individual library patrons and reducing the rate of rise of library per-unit costs, all for the fundamental public purpose of furthering ease of access to and use of the ever-expanding body of worldwide scientific, literary, and educational knowledge and information.”⁷ Among other services, OCLC and its members are responsible for maintaining the WorldCat database (<http://www.worldcat.org/>; last visited December 7, 2020), used by independent and institutional libraries throughout the world. All libraries that are members of OCLC are MARC-compatible. *See, e.g.*, https://help.oclc.org/Metadata_Services/OCLC-MARC_records/About_OCLC-MARC_records (last visited December 7, 2020) (“OCLC-MARC records describes records produced since November 1993.”); <https://www.oclc.org/support/services/worldcat/documentation/cataloging/electronicresources.en.html> (last visited December 7, 2020) (“Like the two superseded OCLC documents, this revised set of guidelines is intended to assist catalogers in creating records for electronic resources in WorldCat, the OCLC Online Union

⁷ Third Article, Amended Articles of Incorporation of OCLC Online Computer Library Center, Inc. (available at <https://www.oclc.org/content/dam/oclc/membership/articles-of-incorporation.pdf>; last visited December 7, 2020).

Catalog. These guidelines pertain to OCLC-MARC tagging (that is, content designation). Cataloging rules and manuals (such as AACR2) govern the content of records. You should implement these guidelines immediately.”).

38. When an OCLC member institution acquires a publication, like the other MARC-compatible libraries discussed above, it creates a MARC record for this publication in its computer catalog system in the ordinary course of its business. MARC records created at the Library of Congress are tape-loaded into the OCLC database through a subscription to MARC Distribution Services daily or weekly. Once the MARC record is created by a cataloger at an OCLC member library or is tape-loaded from the Library of Congress, the MARC record is then made available to any other OCLC members online, and thereby made available to the public. Accordingly, once the MARC record is created by a cataloger at an OCLC member library or is tape-loaded from the Library of Congress, any publication corresponding to the MARC record has been cataloged and indexed according to its subject matter such that a person interested in that subject matter could, with reasonable diligence, locate and access the publication through any library with access to the OCLC bibliographic database or through the Library of Congress.

39. *Fields 008, 005, and 955 in MARC Records as Indicators of Public Accessibility.* When a MARC-compatible library creates an original MARC record for a work, the library records the date of creation of that MARC record in **field 008**,

characters 00 through 05, in the ordinary course of its business. *See* <http://www.loc.gov/marc/bibliographic/bd008a.html> (last visited December 7, 2020). For OCLC member institutions that use OCLC software to create original MARC records, the date of creation in field 008 is automatically supplied by the OCLC software. The MARC record creation date in field 008 thus reflects the date on which, or shortly after which, a work was first acquired and cataloged by the library that created the original MARC record.

40. When other MARC-compatible libraries subsequently acquire their own copies of the same work, as mentioned, they create MARC records in their own computer catalog systems for their copies in the ordinary course of business.⁸ They may use a MARC record previously created for that work (by another MARC-compatible library) to create their own MARC records for their own copies of that same work.⁹ The previously created MARC record used by subsequently-acquiring libraries to create MARC records for their own copies may be obtained through the OCLC bibliographic database, as described above. If, when creating a MARC record to represent its own copy of the work, the subsequently-acquiring library uses the master MARC record in its original form, the subsequently-acquiring library

⁸ Initial contributions to the bibliographic database for a work are called “master records.”

⁹ When a local library uses a master record in OCLC and produces (or downloads) it to the in-house system, the three-character symbol for the subsequent library is added to the holdings for the work.

cannot reenter data into the 008 field; therefore, the date in the 008 field will continue to reflect the date the MARC record was initially created by the originating library. On the other hand, if the subsequently-acquiring library modifies the previously created MARC record when creating its own MARC record for its own copy of the work, the subsequently-acquiring library may enter into the 008 field of its own MARC record the date its own MARC record was created.¹⁰ But the library that created the original MARC record used by the subsequently-acquiring library would still be reflected in the MARC record of the subsequently-acquiring library in field 040, subfield “a”. Thus, the work identified by any MARC record possessed by any MARC-compatible library would have been accessible to the public at least as of the date shown in the 008 field, or shortly thereafter, either from the library that possesses the MARC record itself, or from the originating library indicated in field 040, subfield “a”. As discussed, a MARC-compatible library in the ordinary course of its business creates a MARC record in its own catalog system for a work when it acquires a copy of that work.

41. Moreover, when a MARC record is created by a library for its own copy of a work, **field 005** is automatically populated with the date that MARC record was

¹⁰ This practice is not required by, but is nevertheless consistent with, the MARC standard. Many MARC records exist today whose 008 fields indicate when the first original MARC record for a work was created, rather than when a derivative record was created based on the original MARC record by a subsequently-acquiring library for its own computer catalog system.

created in year, month, day format (YYYYMMDD). See <http://www.loc.gov/marc/bibliographic/bd005.html> (last visited December 7, 2020).¹¹ Thereafter, the library's computer system may automatically update the date in field 005 every time the library updates the MARC record (e.g., to reflect that an item has been moved to a different shelving location within the library). *Id.*¹² Thus, the work identified by any MARC record possessed by any MARC-compatible library would have been accessible to the public at least as of the date shown in the 005 field, or shortly thereafter, from the library that possesses the MARC record itself. As noted, because the 005 field may be updated each time the library updates its MARC record, the work identified by the MARC record may, in fact, have been accessible to the public from that library much earlier than the date indicated in the 005 field.

42. Moreover, MARC records for copies of works available at the Library of Congress can have a **955 field**. See http://www.loc.gov/cds/PDFdownloads/dcm/DCM_2007-03.pdf (last visited December 7, 2020). The 955 field in MARC records obtained from the Library of

¹¹ Some of the newer library catalog systems also include hour, minute, second (HHMMSS).

¹² Field 005 is visible when viewing a MARC record via an appropriate computerized interface. But when a MARC record is printed directly to hardcopy from the OCLC database, the "005" label is not shown. The date in the 005 field instead appears next to the label "Replaced."

Congress provides Local Tracking Information, which is a record of internal steps in the cataloging process followed by the Library of Congress. *Id.* Entries in the 955 field for a particular work are generated by Library of Congress staff as the work progresses through the cataloging process. *Id.* One of the mandatory fields that library staff must enter for each step is the date (in the form of “yyyy-mm-dd” or “yy-mm-dd”) the step was taken. *Id.* Thus, the work identified by a MARC record possessed by the Library of Congress would have been accessible to the public at least as of the earliest date shown in the 955 field, or shortly thereafter, from the Library of Congress.

43. Based on my personal experience as a professional librarian using the MARC and OCLC resources, it has been my experience that both of these resources were continuously operational and available since at least 1992. Indeed, in the course of my work, I have regularly used both of these resources over the past 30+ years, and I have consistently found the information contained within these resources to be complete and reliable. I have never found the date of accessibility as indicated in fields 008, 005, or 955 to be incorrect. And in only a minute number of cases have I found any errors at all in these records – none of which affected my ability to render an accurate opinion as to accessibility, indexing, or subject headings.

B. Journals

44. Catalogers can create MARC records for all types of print, online, and

digital resources. For example, MARC records cover serial publications, including both serially-published monographs and journals. OCLC hosts MARC records for more than 320 million serial publications. Serial publications are those publications that have the same collective title but are intended to be continued indefinitely with enumeration such as a volume or issue number (*e.g.*, magazines, journals, etc.). In the OCLC bibliographic database, the first issue of the serial publication is typically cataloged (*i.e.*, a corresponding MARC record is created), but the date is left open-ended with the use of a punctuation mark such as a dash. OCLC serial publication MARC records represent the entire run of the serial title. With knowledge of the first issue published, future issues can be predicted based on the information provided in the MARC record, for example in field 362. In my extensive professional experience, is it highly unusual for a library to stop collecting and shelving a serial publication prior to the end of its publication run. If a subscription to a serial publication ends its run or is cancelled before the end of its run, the library will denote that it has stopped receiving new volumes by filling in the end date in the MARC record.

45. The handling of printed journal subscriptions is shown on the cover or the first few pages of individual issues. As was the best practice among libraries, issues arrived at a central facility and were immediately received, verified as part of a subscription, checked in, and stamped or labeled with the institution's name and

date. Determining that the issue was part of the library subscription ensured that the entire set of publications for the year had been received so that they could be professionally bound and retained. This process also verified that all of the published issues arrived so that the library staff did not have to request or claim an issue that did not arrive as expected. In large public libraries with branches and multi-campus libraries within academic institutions, the journals were sorted and delivered to the subscribing unit. The new issue was placed in the public area; the older issue was stored so that it remained available.

46. The foregoing process has been standard library practice longer than I have been working in the profession. I first learned the steps in the process in the late 1970s and later supervised it. Although the checking in process has become automated and now links electronically to holdings records for the MARC record for each serial title, the manual placement of a stamp or label and placing the issue in a public area has not changed for 50 years. Unless I note otherwise below in reference to a specific serial publication, it is my expert opinion that this standard protocol was followed for all of the serial publications discussed below.

V. PUBLICATIONS IN THIS PROCEEDING

A. Ghofrani [Exhibit B]

47. Exhibit B attached to my Declaration is a journal article, “Neue Therapieoptionen in der Behandlung der pulmonalarteriellen Hypertonie,” by

Hossein Ardeschir Ghofrani, Robert Voswinckel, Frank Reichenberger, Friedrich Grimminger, and Werner Seeger (hereafter “Ghofrani”), which was published in Volume 30, Number 4 of the journal *Herz*. The Ghofrani article appears on pages 296 to 302 of this issue dated June 2005. Exhibit B is a true and correct copy of the Ghofrani article that I understand is being submitted as an exhibit in this proceeding. Exhibit B is a true and correct copy of the digital article (pages 296-302). I obtained this copy of the article from the publisher through the National Library of Medicine.¹³ Specifically, the text of the article is complete; no pages are missing, and the text on each page appears to flow seamlessly from one page to the next; further, there are no visible alterations to the document. Exhibit B can be found within the custody of a library – a place where, if authentic, a copy of this journal would likely be. Exhibit B is a true and correct copy in a condition that creates no suspicion about its authenticity. It is my opinion that the Ghofrani article was publicly accessible by at least June 1, 2005,¹⁴ as I explain below.

48. The Ghofrani article is also available digitally through the digital repositories *ResearchGate*¹⁵ and *Semantic Scholar*.¹⁶ Publications that arrive

¹³ <https://link.springer.com/article/10.1007/s00059-005-2695-4>

¹⁴ <https://link.springer.com/journal/59/volumes-and-issues/30-4>

¹⁵ https://www.researchgate.net/publication/226718523_Neue_Therapieoptionen_in_der_Behandlung_der_pulmonalarteriellen_Hypertonie

¹⁶ <https://www.semanticscholar.org/paper/Neue-Therapieoptionen-in-der-Behandlung-der-Ghofrani-Voswinckel/601ebbc2511b073424e4ad30a0d3e2e509a146f9>

digitally do not bear a receipt stamp. Therefore, based on my experience working with digital publications, it is my opinion that the Ghofrani article in the journal *Herz* would have been available to users in the National Library of Medicine digitally on June 1, 2005.

49. Attached hereto as Attachment B1 is a true and correct copy of the MARC record for the journal *Herz* in the National Library of Medicine. The library ownership is indicated by the presence of the library's (DNLM) in the 040 field. The library continues to update this MARC record and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment B1 occurred on November 28, 2020, as shown in field 005 ("20201128"). I personally identified and retrieved the MARC record that is Attachment B1 on January 3, 2021.

50. Based on finding a digital copy of Exhibit B in the National Library of Medicine and MARC record in its online library catalog attached as Attachment B1, it is my opinion that the article "Neue Therapieoptionen in der Behandlung der pulmonalarteriellen Hypertonie" by Ghofrani, *et al.* published in the journal *Herz* was available in the National Library of Medicine on June 1, 2005. Attachment B1 also shows that Exhibit B was catalogued with descriptor term reading "Cardiovascular Diseases" (see Attachment B2, National Library of Medicine subject heading D002318) in the 650 field. The 510 index fields indicate that the journal *Herz* and articles within it are indexed in *MEDLINE*, *PubMed*, and *Index*

Medicus.

51. As noted in the holdings information (362 field of Attachment B1), the National Library of Medicine has received the journal *Herz* in print since July 1976 and continues to receive the publication in print and digital versions. In view of the MARC record for Exhibit B, the Ghofrani article was publicly available on June 1, 2005, because the serial title had been received, cataloged, and indexed in the National Library of Medicine and made part of its online catalog database.

52. Attached hereto as Attachment B3 is a true and correct copy of the MARC record for the print version of the journal *Herz* obtained from the OCLC bibliographic database. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment B3, that library code is “NLM,” which means that the MARC record for this serial was cataloged at the National Library of Medicine. As can be seen in the “Entered” field in the MARC record for this exhibit, a cataloger at the National Library of Medicine created OCLC record number 3955104 on June 7, 1978, as shown in the “Entered” field (“19780607”). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment B3 occurred on November 20, 2018, as shown in the “Replaced” field (“20181120”). I personally identified and retrieved the MARC record that is Attachment B3 on January 3, 2021. The “BLvl” entry in Attachment

B3 is “s,” which indicates that the journal *Herz* is a serial publication. Accordingly, the MARC record for Exhibit B corresponds to the journal *Herz* from the time that the serial title began and includes the date of the Ghofrani article.

53. Attachment B3 further includes an entry in field 050 (“RC666”)—as described above, this includes a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system). Attachment B3 further includes an entry in field 060 (“W1 \$b HE986U”), a subject matter consistent with the National Library of Medicine classification system. Attachment B3 further includes an English language descriptor term reading “Cardiovascular system \$x Diseases \$v Periodicals” (see Attachment B4, Library of Congress subject heading sh2009118412) in the 650 field. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment B3 was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entry.

54. Further, as of June 7, 1978, the MARC record attached hereto as Attachment B3 was accessible through any library with access to the OCLC bibliographic database or the online catalog at a library that subscribed to the serial, which means that the corresponding publication was publicly available on or before that same date through any library with access to the OCLC bibliographic database

or through an individual library. Therefore, the Ghofrani article (Exhibit B) was publicly accessible by at least June 1, 2005, because by that time it had been received, cataloged, and indexed at the National Library of Medicine and made part of the OCLC bibliographic database. Attachment B3 indicates that the journal *Herz* as cataloged at the National Library of Medicine is currently available from 82 libraries (“82 other holdings”).

55. In view of the above, this issue of the journal *Herz* was publicly available on June 1, 2005, a little less than one year before the May 15, 2006 priority date, because by that date it had been received, cataloged, and indexed at the National Library of Medicine, made part of the OCLC bibliographic database, and available digitally from SpringerLink. For these reasons, it is my opinion that Exhibit B was published and accessible to the public on June 1, 2005.

B. Remodulin[®] label [Exhibit C]

56. The exhibit filed in this proceeding as Exhibit C is a true and accurate copy of the Remodulin[®] label from the U.S. Department of Health and Human Services database, Drugs @ FDA: FDA Approved Drug Products (<https://www.fda.gov/Drugs/default.htm>) (hereafter called “Remodulin[®] label from FDA”). The U.S. Food and Drug Administration updates its drug establishments

current registration site every business day¹⁷ and did so in 2004.¹⁸ I obtained the document filed as Exhibit C from the Drugs @ FDA: FDA Approved Drug Products site¹⁹ by selecting “search Drugs@FDA” on the database’s home page. I entered the drug name to search for information about Remodulin[®] and clicked the search tab.

57. I clicked on the name of the drug and selected “Remodulin[®]” to see the information available from the “Remodulin[®] 021272, Prescription, United Therap” choice. Then, I highlighted and clicked on the “Approval Date(s) and History, Letters, Labels, Reviews for NDA 021272.” I selected “Supplements ” and scrolled to the bottom of the list. The thirteenth entry is the date November 24, 2004. I clicked on “Review (PDF)” and proceeded to download the file that is publicly available. The label for Remodulin[®] is described on pages 3 through 13 in that downloaded file. Exhibit C is a true and accurate copy of pages 3 through 13 of the Remodulin[®] file (i.e. the label) that I downloaded from Drugs@FDA.

58. In view of the above, the label for Remodulin[®] was publicly available on November 24, 2004, more than one year before the May 15, 2006 priority date, because by that date it had been approved by the U.S. Food and Drug Administration and posted on its public website. For these reasons, it is my opinion that Exhibit C

¹⁷ <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site>

¹⁸ <http://web.archive.org/web/19981212024907/http://www.fda.gov/>

¹⁹ <https://www.accessdata.fda.gov/scripts/cder/daf/>

was published and accessible to the public on November 24, 2004.

C. Voswinckel 2004a (a.k.a. Voswinckel JAHA) [Exhibit D]

59. Exhibit D attached to my Declaration is an abstract, “Pulmonary Arterial Hypertension: New Therapies,” by Robert Voswinckel, Beate Enke, Andre Kreckel, Frank Reichenberger, Stefanie Krick, Henning Galf, Tobias Gessler, Thomas Schmehl, Markus G. Kohstall, Friedrich Grimminger, Hossein A. Ghofrani, Warner Seeger, and Horst Olschewski (hereafter “Voswinckel 2004a”), which was published in the Supplement titled *Abstracts from Scientific Sessions* of Volume 110, Number 17 of the journal *Circulation*. The Voswinckel 2004a abstract appears on page III-295 of this issue dated October 26, 2004. The 2004 Scientific Sessions of the American Heart Association meeting were held on November 7-10, 2004, in New Orleans, Louisiana.²⁰ Exhibit D is a true and correct copy of the Voswinckel 2004a abstract that I understand is being submitted as an exhibit in this proceeding. Exhibit D is a true and correct copy of the abstract (page III-295). I obtained this copy of the abstract from the Ebling Library for the Health Sciences at the University of Wisconsin – Madison. Specifically, the text of the article is complete; no pages are missing, and the text on each page appears to flow seamlessly from one page to the next; further, there are no visible alterations to the document. Exhibit D can be

²⁰ https://www.unboundmedicine.com/medline/citation/16082756/Abstracts_from_the_2004_Scientific_Sessions_of_the_American_Heart_Association__November_7_10_2004_New_Orleans_Louisiana_USA_

found within the custody of a library – a place where, if authentic, a copy of this journal would likely be. Exhibit D is a true and correct copy in a condition that creates no suspicion about its authenticity. It is my opinion that the Voswinckel 2004a abstract was publicly accessible by at least November 26, 2004,²¹ and in any event, more than one year before the May 15, 2006 priority date, as I explain below.

60. Attached hereto as Attachment D1 is a true and correct copy of the MARC record for the journal *Circulation* in the Ebling Library for the Health Sciences at the University of Wisconsin – Madison. The library ownership is indicated by the presence of the library’s code (uwmadisondb) in the fourth 035 field. The library continues to update this MARC record and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment D1 occurred on March 13, 2015, as shown in field 005 (“20150313”). I personally identified and retrieved the MARC record that is Attachment D1 on January 3, 2021.

61. Based on finding a digital copy of Exhibit D1 in the Ebling Library for the Health Sciences at the University of Wisconsin – Madison and MARC record in its online library catalog attached as Attachment D1, it is my opinion that the abstract

²¹ My understanding is further confirmed by a copy of the Voswinckel 2004a article submitted as Ex. 1003 in IPR2017-01621 by Watson Laboratories, Inc. That article was pulled from the British Library, with a receipt date of November 22, 2004. Given that the publisher customarily mailed copies of an issue to all subscribers at that same time, the receipt date by the Ebling Library for the Health Sciences at the University of Wisconsin – Madison would be predictably similar.

“Pulmonary Arterial Hypertension: New Therapies” by Voswinckel, *et al.* published in the Supplement to the journal *Circulation* was available in the Ebling Library for the Health Sciences at the University of Wisconsin – Madison on November 26, 2004. The journal *Circulation* has been published 14 times a year since November 1979 (see field 310 in Attachment D1). Based on the publication frequency, it is reasonable for subscribers to receive new issues within 30 days of the date on the journal cover. Therefore, the Supplement dated October 26, 2004, would have arrived by November 26, 2004. Attachment D1 also shows that Exhibit D was catalogued with two descriptor terms reading “Cardiology \$x Societies” (see Attachment D2, Library of Congress subject heading sh85020214 and Attachment D3, Library of Congress subject heading sh85124175) and “Heart \$x Diseases \$v Periodicals” (see Attachment D4, Library of Congress subject heading sh2009126258) in the 650 fields.

62. As noted in the holdings information (362 field of Attachment D1), the Ebling Library for the Health Sciences at the University of Wisconsin – Madison has received the journal *Circulation* in print since January 1950 and continues to receive the publication in print and digital versions. In view of the MARC record for Exhibit D, the Voswinckel 2004a abstract was publicly available on November 26, 2004, because the serial title had been received, cataloged, and indexed in the Ebling Library for the Health Sciences at the University of Wisconsin – Madison

and made part of its online catalog database.

63. Attached hereto as Attachment D5 is a true and correct copy of the MARC record for the print version of the journal *Circulation* obtained from the OCLC bibliographic database. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment D5, that library code is “MUL,” which means that the MARC record for this serial was cataloged as part of the Minnesota Union List of Serials at the University of Minnesota Libraries. As can be seen in the “Entered” field in the MARC record for this exhibit, a cataloger at the University of Minnesota Libraries created OCLC record number 1554748 on August 17, 1975, as shown in the “Entered” field (“19750817”). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment D5 occurred on July 31, 2020, as shown in the “Replaced” field (“20200731”). I personally identified and retrieved the MARC record that is Attachment D5 on January 3, 2021. The “BLvl” entry in Attachment D5 is “s,” which indicates that the journal *Circulation* is a serial publication. Accordingly, the MARC record for Exhibit D corresponds to the journal *Circulation* from the time that the serial title began and includes the date of the Voswinckel 2004a abstract.

64. Attachment D5 further includes an entry in field 050 (“RC681.A1 \$b C5”)—as described above, this includes a subject matter classification number

consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system). Attachment D5 further includes an entry in field 060 (“W1 CI743”), a subject matter consistent with the National Library of Medicine classification system and an entry in field 082 (“616.105”), a subject matter consistent with the Dewey Decimal classification system. Attachment D5 further includes three English language descriptor terms reading “Cardiology \$v Periodicals” (see Attachment D6, Library of Congress subject heading sh2008117649), “Cardiovascular system \$v Periodicals” (see Attachment D7, Library of Congress subject heading sh85020226 and Attachment D8, Library of Congress subject heading sh85099890), and “Hypertension \$v Periodicals” (see Attachment D9, Library of Congress subject heading sh85063723 and Attachment D8, Library of Congress subject heading sh85099890) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment D5 was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entries.

65. Further, as of August 17, 1975, the MARC record attached hereto as Attachment D5 was accessible through any library with access to the OCLC bibliographic database or the online catalog at a library that subscribed to the serial, which means that the corresponding publication was publicly available on or before

that same date through any library with access to the OCLC bibliographic database or through an individual library. Therefore, the Voswinckel 2004a article (Exhibit D) was publicly accessible by at least November 26, 2004, and in any event at least one year before the May 15, 2006, priority date, because by that time it had been received, cataloged, and indexed at the Ebling Library for the Health Sciences at the University of Wisconsin – Madison and made part of the OCLC bibliographic database. Attachment D5 indicates that the journal *Circulation* as cataloged at the University of Minnesota Libraries is currently available from 1,168 libraries (“1168 other holdings”).

66. In view of the above, this issue of the journal *Circulation* was publicly available on November 26, 2004, and in any event, more than one year before the May 15, 2006 priority date, because by that date it had been received, cataloged, and indexed at the University of Minnesota Libraries, made part of the OCLC bibliographic database, and received at the Ebling Library for the Health Sciences at the University of Wisconsin – Madison. For these reasons, it is my opinion that Exhibit D was published and accessible to the public at least by November 26, 2004.

67. Further, it is my opinion that a person interested and ordinarily skilled in the art (as defined in Section III.B. above), exercising reasonable diligence, could locate this abstract. The journal *Circulation* was available in libraries and widely available to skilled artisans interested in inhaled therapies for pulmonary

hypertension. The “Abstracts from Scientific Sessions 2004” Supplement issue of the *Circulation* was indexed by topic, and one of those topics is the “Pulmonary Arterial Hypertension: New Therapies,” under which Abstracts 1414-1418 are listed. Ex. D at III-295. Voswinckel 2004b is one of these five abstracts (it is Abstract 1414) that a skilled artisan interested in pulmonary hypertension, exercising reasonable diligence in following updates on new pulmonary hypertension research, would be able to locate.

D. Voswinckel 2004b (a.k.a. Voswinckel JESC) [Exhibit E]

68. Exhibit E attached to my Declaration is an abstract, “Inhaled treprostinil is a potent pulmonary vasodilator in severe pulmonary hypertension,” by R. Voswinckel, M.G. Kohstall, B. Enke, T. Gessler, F. Reichenberger, H.A. Ghofrani, W. Seeger, and H. Olschewski (hereafter “Voswinckel 2004b”), which was published in Volume 25, Abstract Supplement of the *European Heart Journal*. The Voswinckel 2004b abstract appears on page 22 of this issue dated August/September 2004. Exhibit E is a true and correct copy of the Voswinckel 2004b abstract that I understand is being submitted as an exhibit in this proceeding. Exhibit E is a true and correct copy of the abstract (page 22). I obtained this copy of the abstract from the University of Iowa Libraries. Specifically, the text of the article is complete; no pages are missing, and the text on each page appears to flow seamlessly from one page to the next; further, there are no visible alterations to the document. Exhibit E

can be found within the custody of a library – a place where, if authentic, a copy of this journal would likely be. Exhibit E is a true and correct copy in a condition that creates no suspicion about its authenticity. It is my opinion that the Voswinckel 2004b abstract was publicly accessible by at least October 15, 2004,²² and in any event, more than one year before the May 15, 2006 priority date, as I explain below.

69. Attached hereto as Attachment E1 is a true and correct copy of the MARC record for the *European Heart Journal* in the University of Iowa Libraries. The library ownership is indicated by the presence of the library's name (IOWA) in the INST field. The library continues to update this MARC record and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment E1 occurred on July 13, 2017, as shown in field 005 ("20170713"). I personally identified and retrieved the MARC record that is Attachment E1 on January 5, 2021.

70. Based on finding a digital copy of Exhibit E in the University of Iowa Libraries and MARC record in its online library catalog attached as Attachment E1, it is my opinion that the abstract "Inhaled treprostinil is a potent pulmonary

²² My understanding is further confirmed by a copy of the Voswinckel 2004b article submitted as Ex. 1046 in IPR2017-01621 by Watson Laboratories, Inc. That article was pulled from the Ebling Library for the Health Sciences at the University of Wisconsin – Madison, with a receipt date of October 15, 2004. Given that the publisher customarily mailed copies of an issue to all subscribers at that same time, the receipt date of the University of Iowa's copy would be predictably similar.

vasodilator in severe pulmonary hypertension” by Voswinckel, *et al.* published in the Supplement to the *European Heart Journal* was available in the University of Iowa Libraries on October 15, 2004. The *European Heart Journal* has been published semimonthly since 2004 (see field 310 in Attachment E2). Based on the publication frequency, it is reasonable for subscribers to receive new issues within 30 days of the date on the journal cover. Therefore, the issue of the *European Heart Journal* dated August/September 2004, would have arrived by October 31, 2004. Attachment E1 also shows that Exhibit E was catalogued with two descriptor terms reading “Cardiology \$v Periodicals” (see Attachment D2, Library of Congress subject heading sh85020214 and Attachment D8, Library of Congress subject heading sh85099890) and “Heart \$x Diseases \$v Periodicals” (see Attachment D4, Library of Congress subject heading sh2009126258) in the 650 fields.

71. As noted in the holdings information (362 field of Attachment E1), the University of Iowa Libraries has received the *European Heart Journal* in print since February 1980 and continues to receive the publication. In view of the MARC record for Exhibit E, the Voswinckel 2004b abstract was publicly available on October 15, 2004, because the serial title had been received, cataloged, and indexed in the University of Iowa Libraries and made part of its online catalog database.

72. Attached hereto as Attachment E2 is a true and correct copy of the MARC record for the print version of the *European Heart Journal* obtained from

the OCLC bibliographic database. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment E2, that library code is “NSD,” which means that the MARC record for this serial was cataloged as part of the National Serials Data Program at the Library of Congress. As can be seen in the “Entered” field in the MARC record for this exhibit, a cataloger at the Library of Congress created OCLC record number 5585193 on October 25, 1979, as shown in the “Entered” field (“19791025”). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment E2 occurred on February 18, 2020, as shown in the “Replaced” field (“20200218”). I personally identified and retrieved the MARC record that is Attachment E2 on January 3, 2021. The “BLvl” entry in Attachment E2 is “s,” which indicates that the *European Heart Journal* is a serial publication. Accordingly, the MARC record for Exhibit E corresponds to the *European Heart Journal* from the time that the serial title began and includes the date of the Voswinckel 2004b abstract.

73. Attachment E2 further includes an entry in field 050 (“RC681.A1 \$b E94”)—as described above, this includes a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system). Attachment E2 further includes an entry in field 060 (“W1 \$b EU636”), a subject matter consistent with the National Library of

Medicine classification system. Attachment E2 further includes an English language descriptor term reading “Cardiology \$v Periodicals” (see Attachment D6, Library of Congress subject heading sh2008117649) in the 650 field. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment E2 was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entry.

74. Further, as of October 25, 1979, the MARC record attached hereto as Attachment E2 was accessible through any library with access to the OCLC bibliographic database or the online catalog at a library that subscribed to the serial, which means that the corresponding publication was publicly available on or before that same date through any library with access to the OCLC bibliographic database or through an individual library. Therefore, the Voswinckel 2004b article (Exhibit E) was publicly accessible by at least October 15, 2004, and in any event at least one year before the May 15, 2006, priority date, because by that time it had been received, cataloged, and indexed at the University of Iowa Libraries and made part of the OCLC bibliographic database. Attachment E2 indicates that the *European Heart Journal* as cataloged at the Library of Congress is currently available from 282 libraries (“282 other holdings”).

75. In view of the above, this issue of the *European Heart Journal* was

publicly available on October 15, 2004, and in any event, more than one year before the May 15, 2006 priority date, because by that date it had been received, cataloged, and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received at the University of Iowa Libraries. For these reasons, it is my opinion that Exhibit E was published and accessible to the public on October 15, 2004.

76. Further, it is my opinion that a person interested and ordinarily skilled in the art (as defined in Section III.B. above), exercising reasonable diligence, could locate this abstract. The *European Heart Journal* was available in libraries and widely available to skilled artisans interested in inhaled therapies for pulmonary hypertension. The abstract supplement of the *European Heart Journal* contains a table of contents, indexed by topic. One of those listed topics is the “Epidemiology and treatment of pulmonary arterial hypertension,” for which Abstracts 215 to 220 are listed. Ex. E at 2. Voswinckel 2004b is one of these six abstracts (it is Abstract 218) that a skilled artisan interested in pulmonary hypertension, exercising reasonable diligence in following updates on new pulmonary hypertension research, would be able to locate.

E. Voswinckel 2006 [Exhibit F]

77. Exhibit F attached to my Declaration is a journal article, “Inhaled Treprostinil for Treatment of Chronic Pulmonary Arterial Hypertension,” by Robert

Voswinckel, Hossein A. Ghofrani, Friedrich Grimminger, Werner Seeger, and Horst Olschewski (hereafter “Voswinckel 2006”), which was published in Volume 144, Number 2 of the *Annals of Internal Medicine*. The Voswinckel 2006 article appears on pages 149-150 of this issue dated January 17, 2006. Exhibit F is a true and correct copy of the Voswinckel 2006 article that I understand is being submitted as an exhibit in this proceeding. Exhibit F is a true and correct copy of the article (pages 149-150). I obtained this copy of the article from the Ebling Library for the Health Sciences at the University of Wisconsin – Madison. Specifically, the text of the article is complete; no pages are missing, and the text on each page appears to flow seamlessly from one page to the next; further, there are no visible alterations to the document. Exhibit F can be found within the custody of a library – a place where, if authentic, a copy of this journal would likely be. Exhibit F are true and correct copies in a condition that creates no suspicion about their authenticity. It is my opinion that the Voswinckel 2006 article was publicly accessible online by at least January 17, 2006,²³ and the print copy was available by at least January 24, 2006, based on University of Wisconsin ownership and receipt stamp on Exhibit F as I explain below.

78. Attached hereto as Attachment F1 is a true and correct copy of the

²³ <https://www.acpjournals.org/doi/abs/10.7326/0003-4819-144-2-200601170-00026?journalCode=aim>

MARC record for the *Annals of Internal Medicine* in the Ebling Library for the Health Sciences at the University of Wisconsin – Madison. The library ownership is indicated by the presence of the library’s code (uwmadisondb) in the fifth 035 field. The library continues to update this MARC record and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment F1 occurred on March 13, 2015, as shown in field 005 (“20150313”). I personally identified and retrieved the MARC record that is Attachment F1 on January 3, 2021.

79. Based on finding a digital copy of Exhibit F in the Ebling Library for the Health Sciences at the University of Wisconsin – Madison and MARC record in its online library catalog attached as Attachment F1, it is my opinion that the article “Inhaled Treprostinil for Treatment of Chronic Pulmonary Arterial Hypertension” by Voswinckel, *et al.* published in the *Annals of Internal Medicine* was available in the Ebling Library for the Health Sciences at the University of Wisconsin – Madison on January 24, 2006. Attachment F1 also shows that Exhibit F was catalogued with a descriptor term reading “Medicine \$v Periodicals” (see Attachment F2, Library of Congress subject heading sh2008107665) in the 650 field.

80. As noted in the holdings information (362 field of Attachment F1), the Ebling Library for the Health Sciences at the University of Wisconsin – Madison has received the *Annals of Internal Medicine* in print since July 1927 and continues to receive the publication. In view of the MARC record for Exhibit F, the

Voswinckel 2006 article was publicly available on January 24, 2006, because the serial title had been received, cataloged, and indexed in the Ebling Library for the Health Sciences at the University of Wisconsin – Madison and made part of its online catalog database.

81. Attached hereto as Attachment F3 is a true and correct copy of the MARC record for the print version of the *Annals of Internal Medicine* obtained from the OCLC bibliographic database. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment F3, that library code is “MUL,” which means that the MARC record for this serial was cataloged as part of the Minnesota Union List of Serials at the University of Minnesota Libraries. As can be seen in the “Entered” field in the MARC record for this exhibit, a cataloger at the University of Minnesota Libraries created OCLC record number 1481385 on July 27, 1975, as shown in the “Entered” field (“19750727”). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment F3 occurred on January 23, 2020, as shown in the “Replaced” field (“20200123”). I personally identified and retrieved the MARC record that is Attachment F3 on January 3, 2021. The “BLvl” entry in Attachment F3 is “s,” which indicates that the *Annals of Internal Medicine* is a serial publication. Accordingly, the MARC record for Exhibit F corresponds to the *Annals of Internal Medicine* from

the time that the serial title began and includes the date of the Voswinckel 2006 article.

82. Attachment F3 further includes an entry in field 050 (“R11 \$b .A84”)—as described above, this includes a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system). Attachment F3 further includes an entry in field 060 (“W1 AN605”), a subject matter consistent with the National Library of Medicine classification system. Attachment F3 further includes an English language descriptor term reading “Medicine \$v Periodicals” (see Attachment F2, Library of Congress subject heading sh2008107665) in the 650 field. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment F3 was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entry.

83. Further, as of July 27, 1975, the MARC record attached hereto as Attachment F3 was accessible through any library with access to the OCLC bibliographic database or the online catalog at a library that subscribed to the serial, which means that the corresponding publication was publicly available on or before that same date through any library with access to the OCLC bibliographic database or through an individual library. Therefore, the Voswinckel 2006 article (Exhibit F)

was publicly accessible by at least January 24, 2006, because by that time it had been received, cataloged, and indexed at the Ebling Library for the Health Sciences at the University of Wisconsin – Madison and made part of the OCLC bibliographic database. Attachment F3 indicates that the *Annals of Internal Medicine* as cataloged at the University of Minnesota Libraries is currently available from 1,475 libraries (“1475 other holdings”).

84. In view of the above, this issue of the *Annals of Internal Medicine* was publicly available online on January 17, 2004, and in print by at least January 24, 2006, because by that date it had been received, cataloged, and indexed at the University of Minnesota Libraries, made part of the OCLC bibliographic database, and received at the Ebling Library for the Health Sciences at the University of Wisconsin – Madison. For these reasons, it is my opinion that Exhibit F was published and accessible to the public on January 17, 2006.

VI. CONCLUSION

85. In signing this Declaration, I recognize that the Declaration will be filed as evidence in a case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

EXHIBIT A

**CURRICULUM VITAE
SYLVIA D. HALL-ELLIS**

EDUCATION

Ph.D., University of Pittsburgh, Pittsburgh, Pennsylvania, 1985
 M.P.S., University of Denver, Denver, Colorado, 2014
 Post Graduate Studies, University of Texas – San Antonio, Texas, 1975-1976
 M.L.S., University of North Texas, Denton, Texas, 1972
 B.A., Rockford University, Rockford, Illinois, 1971

PROFESSIONAL EXPERIENCE

- 1981- Consultant for higher education, non-profit organizations, and corporations.**
- 2002- Adjunct Professor, School of Information, San José State University, San José, California.** Serve as part-time faculty member teaching graduate students in technical services (cataloging, bibliographic control, classification), “core courses,” and special topics.
- 2014-2016 Director, Grants and Resource Development, Colorado Community College System.** Provided leadership and vision to foster the continued growth of rigorous scholarship, innovative projects, and creative work for statewide system, 13 campuses, and 50 teaching sites serving 155,000 students. Responsible for leadership and ensured efficient functioning of contract and grants in compliance with state & federal requirements and successful implementation and management. Served as a subject matter expert and liaison for college Grant Directors for all issues relating to grants and subcontracts.
- 2010-2014 Senior Grant Administrator, Morgridge College of Education, University of Denver (Colorado).** Provided leadership and vision to foster continued growth of rigorous scholarship, innovative research, and creative work in the Morgridge College of Education. Ensure that contract and grants processes function effectively and efficiently for 60 faculty and researchers with a focus on the successful progression and efficient management of grants totaling \$13M. Worked effectively and collegially with Department Chairs and Program Coordinators on operational grant-related management activities and with a broad range of internal and external constituencies. Supported the dissemination and promotion of faculty research and scholarship to outside constituents at conferences and through publications. Assisted Principal Investigators and grant project teams by coaching, mentoring, and financial management.
- 2011-2013 Interim Director & Assistant Dean, Westminster Law Library, Sturm College of Law, University of Denver.** Planned, organized, and directed all administrative activities for the library serving students, faculty, and alumni; oversaw the employment, retention, promotion, transfer and termination of library personnel; represented the library at professional conferences and public meetings; created and promoted a climate and culture of acceptance for new programs and services, a positive high-quality image of the law library, and that reflect the organization’s values, encourage excellent performance, and reward high productivity and innovation; provided leadership and set strategic direction of the organization; ensured that the library provided excellent customer service through solution-oriented staff response to patron needs and by responsiveness and continuous improvement of the organization; promoted, developed, and maintained positive working relationships with colleagues and customers including key stakeholders and groups, higher education institutions, the legal community, other regional libraries and districts statewide, and national library organizations.
- 2007-2014 Associate Professor, Library & Information Science, Morgridge College of Education, University of Denver (Colorado).** Served in leadership role and worked collaboratively in program, college, campus and community environments. Advised and supervised students, taught core and specialized courses at the graduate level in an integrative, student-centered learning environment. Served on LIS, College, and University committees, and maintained

working relationships with colleagues in other academic units and information professionals in the Rocky Mountain region and beyond. Served on and chair doctoral student dissertation committees. Oversaw and facilitated the College and LIS graduate student association.

- 2002-2007** **Assistant Professor, Library & Information Science, College of Education, University of Denver (Colorado).** Served as tenure-track faculty member teaching graduate students in “core courses,” resource description and access, service learning, and independent studies. Advised graduate students, participate on LIS and College committees, and serve on doctoral student dissertation committees. Oversaw and facilitated the LIS graduate student association and alumni association.
- 2000-2002** **Affiliate Faculty, Library & Information Science, College of Education, University of Denver (Colorado).** Served as part-time faculty member teaching graduate students in technical services (cataloging, bibliographic control, classification), “core courses,” and special topics. Oversaw and facilitated the LIS graduate student association and alumni association.
- 2000-2001** **Special Assistant to the Secretary’s Regional Representative, U.S. Department of Education, Region VIII, Denver, Colorado.** Served as the principal advisor and representative of the U. S. Secretary of Education’s Regional Representative (SRR). Ensured the implementation of major goals of the SRR and the Secretary. Provided leadership on behalf of the SRR in contacts with high-level officials in Region VIII requiring sensitive policy interpretation in communication with senior Department officials to solve problems and resolve issues raised by State and local education officials. Served as the primary contact for School-to-Work/Career, Children’s Health Insurance Program, and Safe and Drug-Free Schools. Delivered technical assistance to local education agencies and institutions of higher education in technology, professional development, and school construction.
- 1999-2000** **Catalog Librarian, Jefferson County Public Library, Lakewood, Colorado.** Performed original, copy cataloging and classification of library materials (English and Spanish) using standard library protocols; completed original descriptive cataloging and subject analysis; enhanced brief catalog and authority records in III.
- 1997-1999** **Development Officer, McREL International, Aurora, Colorado.** Served as senior member of corporate management team in strategic planning, development of proposals and contracts, implementation, and evaluation of new services, products, and programs for educational agencies. Provided creative leadership to corporate committees to solicit ideas, identify goals and objectives, plan, develop, present, and evaluate professional development opportunities.
- 1995-1997** **Education Specialist, Education Service Center, Region One, Edinburg, Texas.** Served as member of Administrative Cabinet team in strategic planning, development of proposals and contracts, implementation, and evaluation of telecommunications capabilities, services, products, and programs for 40 school districts serving 283,000 students in 7 counties. Provided creative leadership to regional and state committees to solicit ideas, identify strategic goals and objectives, plan, develop, present, and evaluate funding opportunities and professional development for 400 librarians.
- 1993-1996** **Assistant Professor of Library Science, Sam Houston State University, Huntsville, Texas.** Served a faculty member teaching 400 graduate students in technical services (cataloging, bibliographic control, classification), automation, and networking. Participated in distance education program and coordinated annual conference. Conducted university and Texas Library Association-funded field research focused on library collection development and academic achievement.

- 1992-1993** **Head Librarian, Rocky Mountain College of Art & Design, Denver, Colorado.**
Responsible for the daily operation, selection and acquisition of materials, formulation of policies for library operations, media center, and photography/slides archives. Designed and implemented library automation and delivery of electronic resources to college community.
- 1981-1985** **Development Officer, PRLC, Inc., Pittsburgh, Pennsylvania.** Served as senior member of corporate management team in strategic planning, development of proposals and contracts, implementation, and evaluation of new services, products, and programs for 100 institutional member organizations. Coordinated the development of proposals and contracts totaling \$4,000,000 annually. Provided creative leadership to corporate committees to solicit ideas, identify goals and objectives, plan, develop, present, and evaluate professional development opportunities.
- 1981** **Director of Library Development, Pennsylvania Department of Education, Harrisburg, Pennsylvania.** Responsible for statewide development, technical assistance, professional development, resource sharing, children's services, institutional library services, networking, and state aid program for all libraries throughout the Commonwealth. Functioned as liaison to Governor's Advisory Council, LSCA Advisory Council, District Administrators, private colleges, universities, consortia managers, and network directors. Supervised \$14,000,000 formula-based state aid program and \$3,000,000 grant awards to individual libraries, consortia, and networks.
- 1978-1981** **Assistant Director, Southern Tier Library System, Corning, New York.** Coordinated operation of system-wide programs (technical assistance, professional development, resource sharing, technical services, outreach) to 40 public libraries in 5 counties serving 500,000 residents. Solicited ideas, identified goals, sponsored, and evaluated professional development opportunities and technical assistance sessions.
- 1976-1978** **Division Librarian for Technical Services, Corpus Christi Public Libraries, Corpus Christi, Texas.** Provided leadership in acquisitions, cataloging, serials control, and processing for main library and 4 branches serving 250,000 residents. Participated as senior member of library management team. Compiled and prepared technical evaluations, reports, and statistical analyses of Division operations to measure the achievement and cost of annual goals, objectives, and staff performance.
- 1975-1976** **System Coordinator, San Antonio Major Resource Center, San Antonio, Texas.** Served as senior member of the management team for District X Office, charged to provide technical assistance, resource sharing, media services, and professional development to librarians and staff representing 30 public library jurisdictions in 21 counties serving 1,500,000 residents. Functioned as liaison to System Director, staff, and members of governing bodies with the System Board of Directors and the Texas State Library and Historical Commission. Prepared LSCA grant applications and monitored awards totaling \$1,100,000 annually.
- 1973-1975** **Bilingual Branch Librarian, San Antonio Public Library, San Antonio, Texas.** Worked as librarian providing reference, information, and readers' advisory services in branch serving 50,000 Spanish-speaking residents in southwest San Antonio. Participated in collection development and resource acquisition activities, specializing in children's work, Spanish language resources, and multicultural studies.
- 1972-1973** **Librarian, Holding Institute, Laredo, Texas.** Worked as high school librarian serving 500 boarding students in Spanish-speaking environment of private school. Provided reference, research assistance, and library instruction to students and 35 faculty members.
- 1966-1971** **Rockford Public Library, Rockford, Illinois.** Worked in branches as part-time as a Library Assistant, Clerk, and Page in city library serving 150,000 residents.

PUBLICATIONS

Editor-reviewed Monographs (Completed and in Progress)

Hall-Ellis, Sylvia D., and Mary Beth Weber. *Contemporary Cataloging in an RDA Environment: A Handbook for Students and Practitioners*. Chicago, IL: American Library Association. Under contract & In development.

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- Hall-Ellis, Sylvia D. "The Relationship of Situational Leadership and the Dreyfus Model of Skill Acquisition for Supervisors in Cataloging and Metadata Services." To be submitted to *Library Resources and Technical Services*. In progress.
- Hall-Ellis, Sylvia D. *The Relationship of Core Competencies on Learning Outcomes and Employers' Expectations for Catalog Librarians and Metadata Specialists*. To be submitted to the *Journal of Education for Library and Information Science*. In progress.
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Hall, Sylvia D. *Newspapers on Microfilm: A Listing of Newspapers in Allegheny, Chemung, Schuylers, Steuben, and Yates Counties*. Ithaca, N.Y.: South Central Reference and Research Council, 1981.

Hall, Sylvia D. *OCLC/ILL Subsystem at Southern Tier Library System*. Albany, N.Y.: SUNY/OCLC Network, 1980.

Hall, Sylvia D. *Retrospective Conversion for Major Public Libraries in South Central New York State: A Technical Report*. 2 vols. Corning, N.Y.: Southern Tier Library System, 1979-1980.

Hall, Sylvia D. *The Librarian and the Mexican-American Patron in Texas*. Austin, Tex.: Texas State Library, 1978.

Other Publications

Hall-Ellis, Sylvia D., ed. *Library and Information Science Program Self-Study Document for Accreditation by the American Library Association*. St. Paul, MN: St. Catherine University, 2017. 255 p.

Hall-Ellis, Sylvia D., and Robert O. Ellett, Jr., guest editors. *RDA Testing: Lessons Learned and Challenges Revealed: A Special Issue of Cataloging & Classification Quarterly* 49, no. 7-8 (November 2011).

Hall-Ellis, Sylvia D. and Robert O. Ellett, Jr. *Fundamentals of Cataloging I: An Online ALCTS Course*. Chicago, Ill.: American Library Association, 2009.

Hall-Ellis, Sylvia D., Angela J. Kinney and Martha Ann Bace, editors. *Best Practices in Cataloging Education Identified at the 2007 ALCTS Pre-conference: A Special Issue of the Journal for Library and Information Science Education* 49, no. 2 (Spring 2008).

Hall-Ellis, Sylvia D. *Cataloging Education: A New Emphasis for the Library and Information Science Curriculum*. Presentation delivered to the ALCTS Pre-conference, 132nd Annual Conference, American Library Association, Washington, D.C., June 22, 2007. <http://www.loc.gov/aba/professional/>

Hall-Ellis, Sylvia D. "Cataloger Competencies: Do the Employers Require What the Professors Teach?" Presentation delivered to the ALCTS CCS Heads of Cataloging Discussion Group, 131st Annual Conference, American Library Association, New Orleans, Louisiana, June 26, 2006. <http://dlist.sir.arizona.edu/>

Hall-Ellis, Sylvia D., guest editor, with Deborah S. Grealy, Clara L. Sitter, and Tassos Petrou. *Library Students' Voices in Colorado: An Issue of Colorado Libraries* 31:1 (Spring 2005).

Hall-Ellis, Sylvia D., ed. *Library and Information Science Program Self-Study Document for Accreditation by the American Library Association*. Denver, Colo.: University of Denver, College of Education, 2003. 125 p. with CD-ROM.

Hall-Ellis, Sylvia D. and Deborah S. Grealy, guest editors. *Library Education in Colorado: An Issue of Colorado Libraries* 29, no. 2 (Summer 2003).

Hall-Ellis, Sylvia D., ed. *Library and Information Science Program Self-Study Document for Accreditation by the American Library Association*. Denver, Colo.: University of Denver, College of Education, 2003.

Hall-Ellis, Sylvia D. "Adaptive Furniture for the ADA-Qualified: An Investigative Study." 2001. Unpublished manuscript.

Hall-Ellis, Sylvia D. "Cataloging Electronic Serials: A Study in User Access and Article Delivery." 2001. Unpublished manuscript.

Hall-Ellis, Sylvia D. "E-books: Acquisition and Circulation Issues in Public Libraries." 2001. Unpublished manuscript.

- Hall-Ellis, Sylvia D. "Authority Control and Its Importance in School Library Media Online Catalogs." 1999. Unpublished manuscript.
- Hall, Sylvia D. "Cooperation Improving Service in San Antonio System." *Texas Libraries* XXXVII (Spring 1976): 27-29.
- Hall, Sylvia D. "Summer is Sea Monstrously Fun!" *Texas Library Journal* L (December 1974): 224-226.
- Hall, Sylvia D. "A Brief Annotated Bibliography of Non-book Materials on the Mexican American." *Texas Library Journal* XLVIII (October 1972): 213-232.

Book Reviews

- ALA Book of Library Grant Money*. Ann Kepler, ed. 8th ed. Chicago, IL: American Library Association, 2011. 978-0-8389-1058-0, \$175.00 [*Colorado Libraries*, June 2012]
- Developing a Compensation Plan for Your Library*. Paula M. Singer and Laura L. Francisco, comps. 2nd ed. Chicago, IL: American Library Association, 2009. 978-0-8389-0985-0, \$57.00 [*Colorado Libraries*, March 2012]
- Frugal Librarian*. Carol Smallwood, ed. Chicago, IL: American Library Association, 2011. 978-0-83891-075-7, \$42.00 [*Colorado Libraries*, February 2012]
- Dowlin, Ken. *Getting the Money: How to Succeed in Fundraising for Public and Nonprofit Libraries*. Westport, Conn.: Libraries Unlimited, 2008. 978-1-59158-597-X, \$50.00 [*Colorado Libraries*, February 2009]
- Lundahl, Mats. *Bebo de Cuba; Bebo Valdés y Su Mundo*, by Mats Lundahl. Traducción de Linda Oakeshott Dragó. Barcelona: RBA Libros, 2008. 978-849-86-7259-6, \$33.99 [*Críticas*, November 2008]
- Bonelli, Florencia. *Marlene*, by Florencia Bonelli. Buenos Aires: Aguilar, Altea, Taurus, Alfaguara, 2008. 978-987-04-0995-3, \$24.95 [*Críticas*, October 2008]
- Keret, Etgar. Traducción de Ana María Bejarano. *Pizzería Kamikaze y Otras Relatos*. México, D.F.: Editorial Sexto Piso, 2008. 968-5679-29-0, no price given [*Críticas*, September 2008]
- Littauer, Marita, and Florence Littauer. *Enriquece tu Comunicación*. Miami, Fla.: Editorial Unilit, 2008. 978-0-7899-1521-4, \$11.99 [*Críticas*, August 2008]
- Martínez, Guillermo. *La Muerte Lenta de Luciana B*. New York: Rayo Planeta, 2008. 978-0-06-156551-9, \$14.95 [*Críticas*, May 2008]
- Matthews, Joseph R. *The Evaluation and Measurement of Library Services*. Westport, Conn.: Libraries Unlimited, 2007. 978-1-59158-532-9, \$50.00 [*Colorado Libraries*, April 2008]
- Gómez-Jurado, Juan. *A Masacre de Virginia Tech: Anatomía de una Mente Torturada*. Barcelona: Ediciones El Andén, 2007. 978-84-935789-4-7, €16.50 [*Críticas*, February, 2008]
- Matthews, Joseph R. *Library Assessment in Higher Education*. Westport, Conn.: Libraries Unlimited, 2007. 978-1-59158-531-2, \$45.00 [*Colorado Libraries*, February 2008]
- Chacón, Inma. *La Princesa India: Cuando el Viento Azul*. México: Alfaguara, 2006. 970-770398-9, \$19.95 [*Críticas*, June 2006]
- Vargas Llosa, Mario. *Israel/Palestina: Paz o Guerra Santa*. fotogs. by Morgana Vargas Llosa. Spain/U.S.: Aguilar: Santillana, 2006. 84-03-09691-7, paper, \$19.95 [*Críticas*, May 2006]

- Findlay, Diane. *Digging into Dewey*. Fort Atkinson, Wisc.: Upstart Books, 2005. 978-1-932146-18-9, \$16.95 [Colorado Libraries, May 2006]
- Pequeñas Resistencias 4: Antología del Nuevo Cuento Norteamericano y Caribeño*. Menéndez, Ronaldo, Ignacio Padilla & Enrique del Risco, eds. Madrid: Páginas de Espuma, 2005. 84-95642-59-X, paper, \$36.95 [Críticas, April 2006]
- Rueda, André. *Vengo a Salvar a España: Biografía de Un Franco Desconocido*. Madrid: Nowtilus (Investigación Abierta), 2005. photogs., bibliog. 84-9763-202-8, paper, \$23.95 [Críticas, March 2006]
- Becerra, Ángela. *El Penúltimo Sueño*. 1st ed. Barcelona: Planeta, 2005. 84-08-05795-2, \$25.95. [Críticas, January 2006]
- Aguilar Camín, Héctor. *La Conspiración de la Fortuna*. 1st ed. México: Planeta, 2005. 970-37-0368-2, \$19.95 [Críticas, October 2005]
- México en Sus Libros*. Enrique Florescano with Pablo Mijangos, editors & compilers. 1st ed. México, D.F.: Taurus Aguilar, 2004. 968-19-0783-3, \$16.95 [Críticas, September 2005]
- Historia Económica de México*. Coordinator, Enrique Semo. México: Universidad Nacional Autónoma de México, Editorial Oceano de México, 2004. 13 vols. 970-32-0805+3 (obra completa), \$9.25 each [Críticas, August 2005]
- Czarnowsky, Christyne A. and Michael H. Williams. *Managing Your Wired Workforce: A Practical Guide*. Denver, Colo.: Bradford Pub., 2003. 1-883726-79-4, \$24.95 [Colorado Libraries, 2004]
- Abraham Lincoln*. Colección Grandes Biografías. Madrid: Edimat Libros, 2003. 84-8403-858-0, €4.95 [Críticas, 2004]
- Alponte, Juan María. *Colón: el Hombre, el Navegante, la Leyenda*. México, D.F.: Aguilar, 2003. 968-19-1260-8, \$16.95 [Críticas, 2004]
- Olcese Salvatecci, Alfieri. *Cómo Estudiar con Éxito: Técnicas y Hábitos Para Aprender Mejor*. México, D.F.: Alfaomega Grupo Editor, 2002. 970-15-0764-9 [Críticas, 2003]
- Mujeres Como Islas: Antología de Narradoras Cubanas, Dominicanas, Puertorriqueñas*. Edición: Olga Marta Pérez, Thelma Jiménez, Andrés Blanco D., eds. Santo Domingo, República Dominicana: Ediciones Ferilibro, 2002. 959-209-419-5 [Críticas, 2003]
- Tibol, Raquel. *Los Murales de Diego Rivera: Universidad Autónoma Chapingo*. México, D.F.: Editorial RM, Universidad Autónoma Chapingo, 2002. 968-5208-08-5 [Críticas, 2003]
- Lindsay-Poland, John. *Emperors in the Jungle: the Hidden History of the U.S. in Panama*. Durham, N.C.: Duke University Press, 2003. 0-8223-3098-9, \$18.95 [Críticas, 2003]
- Kaplan, Allison G. and Ann Marlowe Riedling. *Catalog It! A Guide to Cataloging School Library Materials*. Worthington, Ohio: Linworth Pub., 2002. 1-58683-014-7, \$44.95 [Colorado Libraries, 2002]
- Bardach, Ann Louise. *Cuba Confidential: Love and Vengeance in Miami and Havana*. New York: Random, 2002. 0-375-50489-3, \$25.95 [Library Journal, 2002]
- Swan, James. *Fundraising for Libraries: 25 Proven Ways to Get More Money for Your Library*. New York: Neal Schuman, 2002. 1-55570-433-6, \$69.95 [Colorado Libraries, 2002]
- Puig de Lange, Victoria. *Sol Con Agua*. Nashville, Tenn.: Editorial Vistazo/Ediciones Reio Negro, 2002. 0-9724506-0-2, \$17.75 [Críticas, 2002]

- The Encyclopedia of Latin American Politics*. Edited by Diana Kapiszewski; assistant editor, Alexander Kazan. Westport, Conn.: Oryx Press, 2002. 1-57356-306-4, \$74.95 [*Library Journal*, 2002]
- Vargas Lizano, Isabel. *Y Si Quieres Saber de Mi Pasado*. Con la colaboración de J.C. Vales. Madrid: Santillana Ediciones Generales, S.L., 2002. 84-03-09278-4, \$18.95 [*Críticas*, 2002]
- Ruy Sánchez, Alberto. *Los Jardines Secretos de Mogador: Voces de Tierra*. México, D.F.: Alfaguara, S.A., 2001. 968-19-0879-1, \$16.95 [*Críticas*, 2002]
- Chávez, Ricardo and Celso Santajuliana. *El Final de las Nubes*. Barcelona: RBA Libros, S.A., 2001. 84-7901-760-0, \$11.95 [*Críticas*, 2002]
- The Power of Language / El Poder de la Palabra: Selected Papers from the Second REFORMA National Conference*. Edited by Lillian Castillo-Speed and the REFORMA National Conference Publications Committee. Englewood, Colo.: Libraries Unlimited, 2001. 1-563089459, \$35.00 [*Colorado Libraries*, 2001]
- Martínez, Rubén. *Crossing Over: A Mexican Family on the Migrant Trail*. Metropolitan: Holt, 2001. 0-8050-4908-8, \$26.00 [*Library Journal*, 2001]
- Guevara, Ernesto "Che." *The African Dream: the Diaries of the Revolutionary War in the Congo*. Translated from the Spanish by Patrick Camiller. With an introduction by Richard Gott and a foreword by Aleida Guevara March. New York: Grove Press, 2001. 0-8021-3834-9, \$13.00 [*Library Journal*, 2001]
- Cooper, Gail and Garry Cooper. *New Virtual Field Trips*. Englewood, Colo.: Libraries Unlimited, 2001. 1-56308-887-8, \$27.50 [*Colorado Libraries*, 2001]

NATIONAL SERVICE & PROFESSIONAL AFFILIATIONS

American Library Association

Association for Library Collections & Technical Services

Cataloging, Classification, and Metadata Section

ALCTS Editorial Board, Member, 2015-2019

Committee on Cataloging: Description and Access, Member, 2008-2012

Test Site for RDA, Manager, 2009-2011

Nominating Committee, Member, 2007-2008

Committee for Education and Training of Catalogers, Chair, 2006-2007, Member, 2003-2007

Competencies & Education for a Career in Cataloging Interest Group, Chair, 2010-2012; Member, 2010-

President's Program Committee, 2015-2016

Education Committee, Member, 2005-2007

Task Force on Competencies and Education for a Career in Cataloging, Chair, 2007-2009

2007 Annual Meeting Pre-conference, "What They Don't Teach in Library School: Competencies,

Education and Employer Expectations for a Career in Cataloging," Steering Committee Chair

Fundraising Committee, Member, 2004-2006

Office of Diversity

Committee on Diversity, Chair, 2010-2011

Diversity Research Advisory Committee, Member, 2009-2010

Spectrum Scholar Mentor, 2009

Diversity Grants Review Committee, Member, 2007, 2010, 2012

Office of Statistics and Research

Research and Statistics Committee, Member, 2005-2007; Intern, 2003-2005

Library Research Round Table

Membership Committee, 2019-2021

Board of Directors, Member At-Large, 2009-2012

Member, 2003-

Office of Accreditation

Accreditation Panel Member (training completed 2004)

Accreditation Review Panel Member (training completed 2004)

REFORMA

National Board of Directors, 2005-2013

National Fundraising Chair, 2005-2013

National Recruiting and Mentoring Committee, 2008-2010

Colorado Chapter, Secretary, 2004-2005

Colorado Chapter Liaison to National Board of Directors, 2004-2013

Online Audiovisual Catalogers Association (OLAC)

American Association of Law Libraries (AALL)

Colorado Association of Law Librarians (CoALL)

American Association of University Women

Association for Library and Information Science Education (ALISE)

University of Denver ALISE Representative, 2003-2008; 2010-2011

Membership Advisory Committee, 2007-2010

Technical Services Education Special Interest Group, 2003-

Garfield Doctoral Dissertation Award Reviewer, 2012

Garfield Doctoral Dissertation Scholarship Reviewer, 2014

American Association of University Professors (AAUP), 2006-

American Grant Writers Association, 2014-

Grant Professionals Institute, 2016-

National Grants Management Association, 2014-

Grant Reviewer (National and Regional Team Leader), U.S. Department of Education, 1998-

Grant Reviewer, Broadband Technologies Opportunity Program, U.S. Department of Commerce, 2009

Grant Reviewer, Institute of Museum and Library Services, 1998-2000

Grant Reviewer, Colorado Department of Education, 2014-

Grant Reviewer, Colorado State Library, 1998-

Grant Reviewer, American Association of Community Colleges *Working Connections* program, 1999

Peer Reviewer, *Journal for Library and Information Science Education*, 2005-

Peer Reviewer, *Journal of Library Metadata*, 2009

Peer Reviewer, *International Journal of Library and Information Science*, 2011

Regular Columnist, *The Bottom Line*, 2013-2016

Book Reviewer, *Library Journal*, 2001

Book Reviewer, *Críticas*, 2002-2009

Book Reviewer, *Colorado Libraries*, 2000-2012

REGIONAL SERVICE & PROFESSIONAL AFFILIATIONS

Mountain Plains Library Association

Professional Development Grants Committee, Member, 2005-2006

Professional Development Policy and Guidelines Sub-committee Chair, 2006

Colorado Association of Libraries

“Student Voices” Column Editor, *Colorado Libraries*, 2005-2006

Conference Planning Committee, Member, 2002

Technical Services and Automation Division, Chair, 2002-2003; Member, 2000-

Academic Libraries Division, Peer Review Conference Papers Committee, Member, 2007-2009

Education Committee, Member, 1988-1993

Diverse Populations Committee, Member, 2009-2013

SERVICE TO THE UNIVERSITY OF DENVER

Center for Teaching and Learning Faculty Advisory Board, 2007-2008; 2010-2012

Center for Community Engagement and Service Learning Advisory Board, 2007-2012

Faculty Senate

Executive Committee, 2008-2013

Nominations, Rules & Credentials Committee, Chair, 2008-2013; Member 2007-2013

Appointment, Promotion, and Tenure Revision Committee, 2010-2012

Grievance Policy Committee Member, 2007-2010

Law Library Director Search Committee Chair, 2012-2013

PROF Grant Review, College Representative to the University Review Team, 2006, 2008

Project Homeless Connect Evaluations, Principal Investigator, 2006-2009

University Technology Council, 2007-2009

University of Denver Hyde Interviews for Incoming Freshmen, 2003-2012

SERVICE TO THE MORGRIDGE COLLEGE OF EDUCATION

Appointment, Tenure & Review Committee

Member, voting, 2003-2005; 2007- 2009

Chair, Clinical Faculty Promotion & Tenure Policy Subcommittee, 2008-2009

Member, Community Engagement Subcommittee, 2007-2009

Member, Tenure Review Panel, 2003

Advancement and Alumni Relations Committee, Chair, 2003-2007; Member, 2002-2007

College Building Committee Member, 2004-2010

College of Education Student Association, Faculty Advisor, 2004-2007; 2009-2010

Faculty Senator, 2007-2013

Research and Scholarship Committee, Chair, 2008-2009; Member, 2002-2003, 2008-2009

Research and Grant Mentoring Committee, Chair, 2009-2010
Research Task Force Member, 2010-2012
Search Committee Member, Assistant Professor for Curriculum & Instruction, 2010-2011
Workload Task Force Member, 2010-2011

SERVICE TO THE LIBRARY & INFORMATION SCIENCE PROGRAM

Library and Information Science Student and Alumni Association, Faculty Advisor, 2002-2008
ALA Student Chapter, Faculty Advisor, 2005-2008
Beta Phi Mu Phi Chapter, Faculty Advisor, 2004-2014
Steering Committee Member, Accreditation by the American Library Association, 2001-2004
Search Committee Member, Associate Professor for LIS, 2006
Search Committee Chair, Assistant Professors for LIS, 2003, 2005, 2006, 2007
Search Committee Ex-Officio Member, Director for LIS, 2004

SERVICE TO SAM HOUSTON STATE UNIVERSITY

Rio Roundup: South Texas Literature Conference, Conference Coordinator, 1993
External Relations, Fund Raising, Grants Committee, Chair, 1993-1995
Advisory Council Committee, Chair, 1993-1995
Students, Admissions, and Advisement Committee, Chair, 1994
Institutional Effectiveness Committee, Member, 1993-1995

SERVICE TO THE COLLEGE OF EDUCATION AND APPLIED SCIENCE

Faculty Affairs Committee, Member, 1993-1995
Curriculum Committee, Member, 1993-1995
Continuing Education Committee, Member, 1993-1995

SERVICE TO THE COMMUNITY

French Teacher & Student Exchange with Laon, France, Monarch High School, Boulder Valley School District
(Boulder, Colorado), 2017-
Denver/Boulder Games 2022, Board of Directors, Secretary-Treasurer, 2015-2018
United Way Campaign Committee, College of Education, 2006
Arapahoe County, Election Judge for the County Clerk and Recorder, 2000-2005
Arthritis Foundation, Rocky Mountain Chapter, Certified Educator & Trainer, 1999-2008
Bonfils Blood Center, Silver Level Donor, 2000-2016
Denver Museum of Natural History, Docent, 1992
Tech Prep of the Lower Rio Grande Valley, Inc. (Harlingen, Texas) Board of Directors, 1995-1997
Executive Committee, 1996-1997; Chair, Development Committee, 1995-1997; Chair, Fiscal Agency
Committee, 1995-1996; Chair, Colleges and Universities Committee, 1996-1997
Gilpin County (Colorado) Public Library Board of Trustees, 1986-1989; Vice President, 1987-1989
City of Central (Colorado) Economic Development Committee, 1987-1989
Columbine Family Health Centers, Inc. (Nederland and Black Hawk, Colorado) Board of Directors, 1988-1989

CERTIFICATION

Permanent Public Librarian Certificate - Pennsylvania, New York, Texas
Westlaw Expert Witness, 2008-
Certified Grant Writer®, 2016-

AWARDS AND HONORS

Advanced Practitioner for Service Learning and Community Engagement, University of Denver, 2011
Platinum Star Alumnae, College of Information, Library Science & Technologies, University of North Texas, 2009
Commendation for Integration of Technologies in Teaching & Learning Environment, University of Denver, 2006
Outstanding Adjunct Faculty Member Award, College of Education, University of Denver, 2002
Beta Phi Mu, Pi, University of Pittsburgh, 1985
Alpha Lambda Sigma, University of North Texas, 1972

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Albert Nelson Marquis Lifetime Achievement Award, Who's Who in America
Who's Who in American Women
Who's Who of Women Executives
Dictionary of International Biography
Who's Who in the East
Who's Who in the South and Southwest
Who's Who in the World
Who's Who of Online Professionals
Who's Who in Library and Information Science
2,000 Notable Women
Who's Who of Emerging Leaders
Who's Who in Professional and Executive Women
Who's Who in American Education
International Who's Who of Professional and Business Women
International Leaders in Achievement
International Educator of the Year
Who's Who in Finance and Industry
Who's Who in Finance and Business

Invited International and National Conference Presentations

- Driscoll, Margaret, Christy Confetti Higgins, Scott Brown, and Sylvia D. Hall-Ellis. *A View from Within: Open House Tour of Three Canvas Core Courses*. Presentation to be delivered at the School of Information, San José State University Professional Development Seminar, San José, California, October 17, 2019.
- Hall-Ellis, Sylvia D. *Invest in Me -- I'm Your Future: Succession Planning for Libraries*. Keynote presentation delivered at the ALCTS President's Symposium, Boston, Mass., January 8, 2016.
- Seidel, Kent E. and Sylvia D. Hall-Ellis. *Making Grants Work for You: Strategies for Doctoral Students and Early Career Scholars*. Presentation delivered at the University Council for Educational Administration, Early Career Scholars Session, Indianapolis, Ind., November 9, 2013.
- Hall-Ellis, Sylvia D. *So You Want to be a Manager; Leadership Skills and Competencies for Technical Services Managers and Administrators*. Presentation delivered at the 138th Annual Conference, American Library Association, Chicago, Ill., June 29, 2013.
- Seidel, Kent E., Karen S. Riley, Lyndsay Agans, Susan Korach, and Sylvia D. Hall-Ellis. *Making Grants Work for You (Instead of Just Working for Grants)*. A panel discussion delivered at the University Council for Educational Administration, Early Career Scholars Session, Denver, Colo., November 17, 2012.
- Hall-Ellis, Sylvia D. *After the Great TS Reorganization: The Westminster Law Library*. Presentation delivered at the 137th Annual Conference, American Library Association, Anaheim, Calif., June 23, 2012.
- Hall-Ellis, Sylvia D. *Conversations with Catalogers in the 21st Century*. A panel discussion sponsored by the ALCTS Competencies for a Career in Cataloging Interest Group, delivered at the 137th Annual Conference, American Library Association, Anaheim, Calif., June 22, 2012.
- Hall-Ellis, Sylvia D., moderator. *Mid-Career Leaders Program*. A panel discussion sponsored by the ALA Committee on Diversity delivered at the 136th Annual Conference, American Library Association, New Orleans, La., June 26, 2011.
- Hall-Ellis, Sylvia D., moderator. *Diversity Town Hall*. A community conversation sponsored by the ALA Committee on Diversity delivered at the 136th Annual Conference, American Library Association, New Orleans, La., June 24, 2011.
- LaBarre, Kathryn, Sylvia D. Hall-Ellis, Karen Anderson, Rick Hasenyager, Christopher Cronin, and Penny Baker. *Briefings from RDA Test Participants*. A panel discussion delivered at the Midwinter Conference, American Library Association, San Diego, Calif., January 7, 2011.
- Miksa, Shawne, Marjorie Bloss, and Sylvia D. Hall-Ellis. *Educating the Next Generation of Catalogers: Teaching RDA*. A panel discussion delivered at the 97th Annual Conference, Association for Library and Information Science Education, San Diego, Calif., January 7, 2011.
- Hall-Ellis, Sylvia D., Robert Maxwell, John Hostage, and George Prager. *RDA Panel: What Cataloging Managers Need to Know*. Presentation delivered at the 103rd Annual Conference, American Association of Law Librarians, Denver, Colo., July 12, 2010.
- Hall-Ellis, Sylvia D. and Stacey L. Bowers. *Catalogers in the RDA Environment: Skill Sets, Expectations and Challenges*. Presentation delivered at the 103rd Annual Conference, American Association of Law Librarians, Denver, Colo., July 11, 2010.
- Hall-Ellis, Sylvia D. *Comfortable in Your Cataloging and Metadata Specialist Skin? Or, So You Want to Hire a Cataloger*. Presentation delivered to the ALCTS Research Group at the 134th Annual Conference, American Library Association, Chicago, Ill., July 11, 2009.

- Perez, Megan, Sylvia D. Hall-Ellis, and Denise Anthony. *From Novice to Expert: Collaboration for Succession Planning*. A “hot topic” presentation delivered at the 14th ACRL Conference, Seattle, Wash., March 13, 2009.
- Hall-Ellis, Sylvia D. *Cataloging in the RDA Environment: Skill Sets, Expectations and Challenges*. Presentation delivered to the ALCTS Research and Publications Committee at the Midwinter Conference, American Library Association, Denver, Colo., January 24, 2009.
- Hall-Ellis, Sylvia D. *LIS Cataloging Education for the 21st Century: Expectations and Challenges*. A panel discussion held at the 95th Annual Conference, Association for Library and Information Science Education, Denver, Colo., January 23, 2009.
- Chu, Clara, Sylvia D. Hall-Ellis, and Mark Winston. *The Doctoral Degree & Building a Career*. A panel discussion delivered at the ALA Office of Diversity Spectrum Doctoral Fellows E.J. Josey Leadership Institute, Midwinter Conference, American Library Association, Denver, Colo., January 20, 2009.
- Hall-Ellis, Sylvia D. and Robert O. Ellett, Jr. *Fundamentals of Cataloging Course: An Overview of the ALCTS Online Course*. Presentation delivered to the ALCTS Big Heads Group, 133rd Annual Conference, American Library Association, Anaheim, Calif., June 30, 2008.
- Hall-Ellis, Sylvia D. *Employers' Expectations for Technical Services Librarians: What We Don't Know*. Presentation delivered to the ALCTS Research and Publications Committee Program, 133rd Annual Conference, American Library Association, Anaheim, Calif., June 28, 2008.
- Hall-Ellis, Sylvia D., Virginia R. Maloney, and Mary Stansbury. *Institutional Responses to Engaged Scholarship: The Carnegie Foundation Engaged University Classification at Two Universities*. Presentation delivered to the 94th Annual Conference, Association for Library and Information Science Education, Philadelphia, Pa., January 11, 2008.
- Hall-Ellis, Sylvia D. *Puzzles, Problems, and Predicaments*. Presentation delivered to the ALCTS Research Discussion Group, 132nd Annual Conference, American Library Association, Washington, D.C., June 23, 2007.
- Hall-Ellis, Sylvia D. *Cataloging Education: A New Emphasis for the Library and Information Science Curriculum*. Presentation delivered to the ALCTS Pre-conference, 132nd Annual Conference, American Library Association, Washington, D.C., June 22, 2007. <http://www.loc.gov/catdir/cpsocareercat.html>
- Ellett, Jr., Robert O. and Sylvia D. Hall-Ellis. *Copy Cataloging Done Smarter*. Presentation delivered to the International Conference on Interdisciplinary Information Sciences and Technologies (InSciT2006), October 25-28, 2006.
- Hall-Ellis, Sylvia D. and Robert O. Ellett, Jr. *Cooperative Cataloging: Challenges and Opportunities for Defense Libraries*. Presentation delivered to the 1st Annual Conference of Defense Libraries, Spanish Ministry of Defense, Madrid, Spain, July 7, 2006.
- Hall-Ellis, Sylvia D. *Cataloger Competencies: Do the Employers Require What the Professors Teach?* Presentation delivered to the ALCTS CCS Heads of Cataloging Discussion Group, 131st Annual Conference, American Library Association, New Orleans, La., June 26, 2006.
- Grealy, Deborah S. and Sylvia D. Hall-Ellis. *From Research to Practice: The Scholarship of Teaching and Learning in LIS Education*. Presentation delivered to the at the 92nd Annual Conference, Association for Library and Information Science Education, San Antonio, Tex., January 18, 2006.
- Hall-Ellis, Sylvia D. *Employers' Expectations for Entry-Level Catalogers: What Position Announcement Data Indicate*. Research paper delivered to the Technical Services Special Interests Group, 91st Annual Conference, Association for Library and Information Science Education, Boston, Mass., January 12, 2005. <http://dlist.sir.arizona.edu/>

Hall-Ellis, Sylvia D. *Common Errors in MARC Records Prepared by LIS Students: What Does It Mean?* Research paper delivered to the ALCTS CCS Cataloging Norms Discussion Group, Mid-Winter Conference, 90th American Library Association, San Diego, Calif., January 10, 2004.

Hall-Ellis, Sylvia D. *Visual Arts as Foundation for Successful Library Automation: The Rocky Mountain College of Art & Design Experience*. Paper delivered at the 6th Annual Conference of Higher Education, Charleston, S. C., 1993.

Hall, Sylvia D. *Design Elements for Bibliographic Databases: An Overview*. Paper delivered at the 14th Online National Conference, New York, 1983.

Invited Regional Conference Presentations

Hall-Ellis, Sylvia D., Hudson, Christopher D., Brittany Cronin, and Kathryn Michaels. "The Colorado Law Project: Meeting the Public's Need for Legal Information." Panel discussion delivered at the Mountain Plains Library Association Conference, Billings, Mont., April 9, 2011.

Grealy, Deborah S. and Sylvia D. Hall-Ellis. *Education for Information Professionals in New Mexico: Library & Information Science Graduate Education at the University of Denver*. Presentation delivered at the New Mexico Library Education Summit, Las Vegas, N.M., September 26, 2005.

Hall-Ellis, Sylvia D. *Public Library-School Library Partnerships*. Presentation delivered at the 3rd Annual Colorado Association of Libraries Conference with the Mountain Plains Library Association, Denver, Colo., October 22, 2004.

Hall-Ellis, Sylvia D. *Learn All You Can – Educational Partnership Opportunities for the Lewis and Clark Bicentennial Commemoration*. Paper delivered at the 3rd Annual Lewis and Clark Bicentennial Council National Planning Conference, Bismarck, N.D., April 26, 1998.

Invited State Conference Presentations

Grealy, Deborah S. and Sylvia D. Hall-Ellis. *Academic Library Leadership Changes: Using Succession Planning and Mentoring*. Presentation delivered at the Minnesota Library Education Conference, St. Cloud, Minn., October 10, 2013.

Hall-Ellis, Sylvia D., Merrie Valliant, and Melissa Powell. *RDA: What Is It and What Do You Need To Do With It At Your Library?* Presentation delivered at the Colorado Library Consortium Spring Conference, Ft. Morgan, Colo., April 26, 2013.

Hall-Ellis, Sylvia D. *Service Learning and the Library & Information Science Graduate Education at the University of Denver*. Presentation delivered at the 4th LEADS Scholars Orientation, Denver, Colo., August 5, 2009.

Hall-Ellis, Sylvia D. *Service Learning: Enhancement to Library & Information Science Graduate Education at the University of Denver*. Presentation delivered at the 3rd LEADS Scholars Orientation, Denver, Colo., June 2008.

Hall-Ellis, Sylvia D. *Law Librarianship: A Community Conversation*. Sponsored by the Colorado Association of Law Libraries. Paper delivered at the Colorado Supreme Court Library, Denver, Colo., May 14, 2008.

Hall-Ellis, Sylvia D. *Opportunities and Challenges in Law Librarianship: A Community Conversation*. Presentation delivered at the Sturm College of Law, Denver, Colo., November 7, 2007.

Hall-Ellis, Sylvia D. *Grant Writing Resources for Nursing Professionals*. Presentation delivered at the Presbyterian / St. Luke's Health One Medical Center 1st Annual Research Symposium, Denver, Colo., October 17, 2007.

- Hall-Ellis, Sylvia D. *Project Homeless Connect 4 Event Evaluation – Insights and Lessons Learned*. Presentation delivered at the Homelessness Research Symposium: What is DU Doing about Homelessness in Denver, Denver, Colo., September 14, 2007.
- Hall-Ellis, Sylvia D. *Service Learning and the Library & Information Science Graduate Education at the University of Denver*. Presentation delivered at the 2nd LEADS Scholars Orientation, Denver, Colo., August 10, 2007.
- Hall-Ellis, Sylvia D. *Education for Information Professionals in a Digital Environment: Library & Information Science Graduate Education at the University of Denver*. Presentation delivered at the 15th Spring Mountains and Plains Parapros Conference, Denver, Colo., February 24, 2007.
- Hall-Ellis, Sylvia D. *Public Library Service to Spanish-Speaking and Latino Residents in Denver: A Case Study*. Presentation delivered at the 4th Annual Colorado Association of Libraries Conference, Denver, Colo., November 10, 2005.
- Hall-Ellis, Sylvia D. *Education for Information Professionals in a Digital Environment: Library & Information Science Graduate Education at the University of Denver*. Presentation delivered at the 14th Annual Mountains and Plains Parapros Conference, Aurora, Colo., July 29, 2005.
- Hall-Ellis, Sylvia D. *Educational Opportunities: Library & Information Science Graduate Education at the University of Denver*. Presentation delivered at the 13th Annual Mountains and Plains Parapros Conference, Centennial, Colo., August 6, 2004.
- Hall-Ellis, Sylvia D. *Library Education & Training: Focus on the West: An LIS Faculty Member's Personal Response*. Presentation delivered at the 1st Annual Colorado Association of Libraries Conference, Keystone, Colo., October 18, 2002.
- Hall-Ellis, Sylvia D. *Grant Writing for School Librarians*. Presentation delivered at the 2002 Annual Colorado Education Media Association Conference, Colorado Springs, Colo., February 15, 2002.
- Hall-Ellis, Sylvia D. *Grants – Opportunities for the Future*. Paper delivered at the Southeast Regional Accountability Annual Conference, Lamar, Colo., November 12, 1998.
- Hall-Ellis, Sylvia D. *The Texas Library Connection and Interlibrary Loan: An Experiment in Resource Sharing*. Paper delivered at the Texas Computer Educators' Association Annual Conference, Austin, Tex., February 6, 1997.
- Hall-Ellis, Sylvia D. *Finding Grant Sources on the Internet: A Guide for Librarians*. Paper delivered at the 2nd Annual Institute for School Library Personnel, Pharr-San Juan-Alamo North High School, Pharr, Tex., July 29, 1996.
- Hall-Ellis, Sylvia D. *Mathematical and Logical Thinking: A Critical Intelligence*. Paper delivered at the 3rd Annual Paraprofessional Conference at the University of Texas - Pan American, Edinburg, Tex., March 8, 1996.
- Hall-Ellis, Sylvia D. *Cataloging Trends and Issues: Update Session*. Paper delivered at the 1st Annual Institute for School Library Personnel, South Texas Community College, McAllen, Tex., July 19, 1995.
- Hall-Ellis, Sylvia D. *Grant Writing: Tips and Encouragement for School Librarians*. Paper delivered at the 1st Annual Institute for School Library Personnel, South Texas Community College, McAllen, Tex., July 18 and 19, 1995.
- Hall-Ellis, Sylvia D. *How to Become an Expert Grant Writer*. Paper delivered at the 3rd Annual High School Principals' Academy, South Padre Island, Port Isabel, Tex., June 19, 1995.

Hall-Ellis, Sylvia D. *Texas Library Study: Results from Regions I and II*. Paper delivered at the 3rd Annual Technology Conference, Texas A&M University, College Station, Tex., November 18, 1994.

Hall-Ellis, Sylvia D. *Academic Achievement and Middle School Students*. Paper delivered at the 8th Annual Young Adult Conference, Sam Houston State University, Huntsville, Tex., November 5, 1994.

Hall-Ellis, Sylvia D. *Multimedia Resources for Library Leaders*. Paper delivered at the Institute for Librarians in A Multicultural Environment, Sam Houston State University, Huntsville, Tex., June 10, 1994.

Hall-Ellis, Sylvia D. *Finding the Resource: Empowering the User, or, the Case for Curriculum Based Subject Access to Learning Resource Center Collections*. Paper delivered at the 81st Annual Texas Library Association Conference, Corpus Christi, Tex., April 12-16, 1994.

Hall-Ellis, Sylvia D. and William H. Pichette. *Sam Houston State University Makes Use of OCLC/AMIGOS Collection Analysis CD*. Paper delivered at the 81st Annual Texas Library Association Conference, Corpus Christi, Tex., April 12-16, 1994.

Hall, Sylvia D. *Funding and Library Development in Pennsylvania: A Symbiotic Relationship*. Paper delivered at the Annual Graduate Student Colloquia, University of Pittsburgh, School of Library and Information Science, 1982.

Hall, Sylvia D. *Leadership for Public Library Trustees*. Paper delivered for the Trustees Division, Pennsylvania Library Association Annual Conference, Lancaster, Penn., 1981.

Seminar and Professional Development Presentations

Taylor, Meredith, and Sylvia D. Hall-Ellis. *Talent Management and Succession Planning*. ALCTS eForum, held March 22, 2017.

Hirsh, Sandra, Heather O'Brien, Michelle Holschuh Simmons, Michael Krasulski, and Sylvia D. Hall-Ellis. *Information Services Today: An Introduction. Part 3: Information Services: Roles in the Digital Age*. Rowan and Littlefield in partnership with Library Journal webinar, recorded February 5, 2015.

Hall-Ellis, Sylvia D. and Jennifer Sweda. *Copy Cataloging in an RDA Environment*. ALCTS eForum, held May 14 and 15, 2013.

Hall-Ellis, Sylvia D. *Law Librarianship: A Community Conversation*. Sponsored by the Colorado Association of Law Libraries, presented at the Colorado Supreme Court Library, Denver, Colo., May 14, 2008.

Hall-Ellis, Sylvia D. and Beatrice Z. Gerrish. *Reading and Libraries: Recent Research in Reading*. Presentation at the Ricks Center for Gifted Education, Denver, Colo., March 4, 2008.

Hall-Ellis, Sylvia D. *Cataloger Competencies: Do the Employers Require What the Professors Teach?* Presentation for the School of Library and Information Science, San José State University, February 12, 2008.

Hall-Ellis, Sylvia D. and Robert O. Ellett, Jr. *Cooperative Cataloging: Rules, Tools, and Conventions for Building a Multi-institutional Catalog*. Sponsored for the Spanish Ministry of Defense, Madrid, Spain, July 10, 2006.

Hall-Ellis, Sylvia D. *Cash for Kids: Grant Writing Opportunities for Youth Services Librarians*. Sponsored by the Colorado Young Adult Librarians; presented at Bemis Memorial Library, Littleton, Colo., November 13, 2002.

Hall-Ellis, Sylvia D. *MARC Records and Authority Control: Planning for Bibliographic Database Migration*. Sponsored and held at the Douglas County Public Library, Castle Rock, Colo., May 28, 2002.

- Hall-Ellis, Sylvia D. *Grant Writing: A Refresher for Librarians*. Sponsored by Library and Information Science Program, College of Education, University of Denver; presented at University Center at Chaparral, August 12, 2000.
- Hall-Ellis, Sylvia D. *Shaking the Money Tree – Basic Grant Writing for Colorado Educators*. Sponsored by the Office of Educational Telecommunications of the Colorado Department of Education.
Pikes Peak Community College, Colorado Springs, Colo., November 16, 1998.
Pueblo School District 60, Pueblo, Colo., November 12, 1998.
University of Northern Colorado, Greeley, Colo., November 10, 1998.
United Technology Educational Partnership, Grand Junction, Colo., November 9, 1998.
- Hall-Ellis, Sylvia D. *Cataloging Multimedia, Kits, Globes and Map Materials in USMARC*. Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., April 24, 1997 and December 12, 1996.
- Hall-Ellis, Sylvia D. *New Standards for School Library Media Centers*. Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., April 15, 1997.
- Hall-Ellis, Sylvia D. *The School Library Media Specialist in the 21st Century: Visions for the Future*. Sponsored and hosted by Pharr-San Juan-Alamo Independent School District, Pharr, Tex., April 4, 1997.
- Hall-Ellis, Sylvia D. *Cataloging Sound Recordings and Audio Materials in USMARC*. Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., March 20, 1997 and November 21, 1996.
- Hall-Ellis, Sylvia D. *Evaluating and Selecting CD-ROMs for School Library Media Collections*. Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., March 18, 1997.
- Hall-Ellis, Sylvia D. *Cataloging Audiovisual Materials in USMARC*. Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., February 27, 1997, November 7, 1996 and October 24, 1996.
- Hall-Ellis, Sylvia D. *Introduction to Dialog: Basic Searching Strategies*. Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., February 14, 1997.
- Hall-Ellis, Sylvia D. *Cataloging Books in USMARC*. Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., January 30, 1997, October 10, 1996, September 26, 1996 and August 8, 1996.
- Hall-Ellis, Sylvia D. *Advanced Internet Searching Techniques for Librarians*. Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., January 21, 1997.
- Hall-Ellis, Sylvia D. *Texas Library Connection Full-Text Searching*. Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., December 13, 1996 and October 25, 1996.
- Hall-Ellis, Sylvia D. *Developing Evaluation Strategies for Grants and Proposals*. Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., December 10, 1996.
- Hall-Ellis, Sylvia D. *Developing Needs Assessment for Grants and Proposals*. Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., November 12, 1996.
- Hall-Ellis, Sylvia D. *Texas Library Connection Union Catalog Searching*. Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., November 8, 1996 and September 6, 1996.
- Hall-Ellis, Sylvia D. *Grant Resources on the Internet*. Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., October 23, 1996.
- Hall-Ellis, Sylvia D. *Preparing a Response to the Telecommunications Infrastructure Fund Board: Needs Assessment, Professional Development Framework, and Evaluation Strategies*. Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., October 16, 1996.

- Hall-Ellis, Sylvia D. *Texas Library Connection: Building the Districtwide Bibliographic Database*. Sponsored and hosted by Mercedes Independent School District, Mercedes, Tex., September 13, 1996 and August 8, 1996. Sponsored and hosted by Los Fresnos Consolidated Independent School District, Los Fresnos, Tex., August 12, 1996.
- Hall-Ellis, Sylvia D. *School-to-Work and Special Education: An Inclusive Partnership for Success*. Sponsored and hosted by the Office of Special Education, Region One Education Service Center, Edinburg, Tex., September 11, 1996.
- Hall-Ellis, Sylvia D. *Telecommunications Infrastructure Fund Board: An Overview of Funding for Secondary Schools*. Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., August 31, 1996.
- Hall-Ellis, Sylvia D. *Cataloging Books, Multimedia, and Realia in USMARC*. Sponsored and hosted by Edinburg Consolidated Independent School District, Edinburg, Tex., August 6, 1996.
- Hall-Ellis, Sylvia D. *Internet Resources for Grant Writers*. Sponsored and hosted by Region One Education Service Center, Edinburg, Tex., April 20, 1996.
- Hall-Ellis, Sylvia D. *Enhanced Grant Writing Skills for Mathematics Educators: Writing Skills for Campus Teams*. Sponsored and hosted by the Office of General Education, Region One Education Service Center, Edinburg, Tex., March 22, 1996.
- Hall-Ellis, Sylvia D. *Internet Resources for Grant Writers*. Sponsored and hosted by the College of Education and Applied Science, Sam Houston State University, Huntsville, Tex., March 9, 1996.
- Hall-Ellis, Sylvia D. *Grant Writing for Mathematics Educators: A Development Process for Campus Teams*. Sponsored and hosted by the Office of General Education, Region One Education Service Center, Edinburg, Tex., March 4, 1996.
- Hall-Ellis, Sylvia D. *Shaking the Money Tree: Preparing Successful Technology Grant Applications*. Sponsored and hosted by the Office of Technology and Media Services, Region One Education Service Center, Edinburg, Tex., February 29, 1996 and April 29, 1996.
- Hall-Ellis, Sylvia D. *District-wide Technology Planning: Technical Assistance for the Texas Education Agency Initiative*. Sponsored and hosted by the Office of Technology and Media, Region One Education Service Center, Edinburg, Tex., February 2, 1996.
- Hall-Ellis, Sylvia D. *Enhanced Grant Writing Skills*. Sponsored and hosted by Pharr-San Juan-Alamo Independent School District, Pharr, Tex., January 27, 1996.
- Hall-Ellis, Sylvia D. *United States Copyright Act of 1976, Video Transmissions, Computer Software and the Internet*. Sponsored and hosted by the Office of Technology and Media, Region One Education Service Center, Edinburg, Tex., January 24, 1996.
- Hall-Ellis, Sylvia D. *The Grant Writing Development Process*. Sponsored and hosted by Pharr-San Juan-Alamo Independent School District, Pharr, Tex., January 20, 1996.
- Hall-Ellis, Sylvia D. *MARC Cataloging of Materials for Library Media Centers*. Sponsored and hosted by the Office of Media Services, Region One Education Service Center for the Donna Independent School District, Donna, Tex., August 17, 1995.
- Hall-Ellis, Sylvia D. *Classification*. Sponsored by AJ Seminars, Rockville, Maryland; presented at University Hilton Hotel, Houston, Tex., May 10, 1995.

- Hall-Ellis, Sylvia D. *Library Technical Services*. Sponsored by AJ Seminars, Rockville, Maryland; presented at University Hilton Hotel, Houston, Tex., April 26, 1995.
- Hall-Ellis, Sylvia D. *Grant Writing: An Introduction for Public School Administrators*. Sponsored and hosted by the Office of Administrative Services, Region One Education Service Center, Edinburg, Tex., April 19, 1995.
- Hall-Ellis, Sylvia D. *The School Library Media Specialist in the 21st Century: Visions for the Future*. Sponsored and hosted by the United Independent School District, Laredo, Tex., March 31, 1995.
- Hall-Ellis, Sylvia D. *Using USMARC*. Sponsored by AJ Seminars, Rockville, Maryland; presented at University Hilton Hotel, Houston, Tex., March 29, 1995.
- Hall-Ellis, Sylvia D. *Library Media Center Policies and Guidelines: How to Prepare for School Board Adoption*. Sponsored and hosted by the Office of Technology and Media Services, La Joya Independent School District, La Joya, Tex., March 10, 1995.
- Hall-Ellis, Sylvia D. *Developing District-wide Policies and Guidelines for Library Media Centers*. Sponsored and hosted by the Office of Technology and Media Services, La Joya Independent School District, La Joya, Tex., January 10, 1995.
- Hall-Ellis, Sylvia D. *MARC Cataloging of Audiovisual Materials for Library Media Centers*. Sponsored and hosted by the Office of Library Media and Technology Services, Cypress-Fairbanks Independent School District, Houston, Tex., December 1, 1994.
- Hall-Ellis, Sylvia D. *The School Library Media Specialist in the 21st Century: Visions for the Future*. Sponsored and hosted by United Independent School District, Laredo, Tex., October 14, 1994.
- Hall-Ellis, Sylvia D. *The School Library Media Specialist in the 21st Century: Visions for the Future*. Sponsored and hosted by the Laredo Independent School District, Laredo, Tex., October 7, 1994.
- Hall-Ellis, Sylvia D. *MARC Cataloging for Library Media Centers*. Sponsored by the Office of Library Media and Technology Services, Cypress-Fairbanks Independent School District, Houston, Tex., October 5, 1994.
- Hall-Ellis, Sylvia D. *Jump to the Head of the Class: Undergraduate Library Resources Available at Sam Houston State University*. Sponsored by the Office of the Associate Vice President for Student Services, Sam Houston State University, Huntsville, Tex., October 4, 1994.
- Hall-Ellis, Sylvia D. *CD-ROMs - 1994's Newest and the Best for Secondary Level Media Centers*. Sponsored and hosted by Clear Lake Independent School District, Houston, Tex., June 3, 1994.
- Hall-Ellis, Sylvia D. *Introduction to Classification*. Sponsored by AJ Seminars, Rockville, Maryland; presented at Holiday Inn, Market Center, Dallas, Tex., May 18, 1994.
- Hall-Ellis, Sylvia D. *Basic Descriptive Cataloging*. Sponsored by AJ Seminars, Rockville, Maryland; presented at University Hilton Hotel, Houston, Tex., May 4, 1994.
- Hall-Ellis, Sylvia D. *Shaking the Money Tree - Part II: Writing Successful Grant Applications*. Sponsored by Donna Independent School District, Donna, Texas, and Region One Education Service Center Edinburg, Texas; presented at South Texas Community College Library, McAllen, Tex., April 29, 1994.
- Hall-Ellis, Sylvia D. *Using MARC*. Sponsored by AJ Seminars, Rockville, Maryland; presented at Holiday Inn, Market Center, Dallas, Tex., April 6, 1994.
- Hall-Ellis, Sylvia D. *Automated Authority Control*. Sponsored by AJ Seminars, Rockville, Maryland; presented at University Hilton Hotel, Houston, Tex., March 23, 1994.

Sylvia D. Hall-Ellis, Ph.D.
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Hall-Ellis, Sylvia D. *Automating the District School Library Media Centers: Choices and Opportunities*. Sponsored and hosted by the Office of Technology and Library Media Services, Fort Bend Independent School District, Sugar Land, Tex., March 4, 1994.

Hall-Ellis, Sylvia D. *Shaking the Money Tree - Part I: Preparing Successful Grant Applications*. Sponsored and hosted by the Office of Library Media Services, Donna Independent School District, Donna, Tex., February 4, 1994.

GRADUATE COURSES TAUGHT

San José State University, School of Library and Information Science

- INFO 249 – Advanced Cataloging and Classification (Fall 2015, 2016; Summer 2016)
- INFO 287 – Special Topics in Cataloging and Classification (Spring 2017, 2018, 2019, 2020, 2021; Fall 2020)
- LIBR 248 – Beginning Cataloging and Classification (Summer 2002, 2003, 2004, 2005, 2006)
- LIBR 249 – Advanced Cataloging and Classification (Summer 2003; Fall 2014; Summer 2015)

University of Denver, University College

- Grant Writing Certificate Seminar for Non-Profit Organizations (Fall 2020, Spring 2021)

University of Denver, Morgridge College of Education

- HED 5991 – Grant Writing in Higher Education (Spring 2011)
- LIS 4010 – Organization of Information (Fall 2002, 2003, 2004, 2005, 2006, 2009; Winter 2005; Spring 2004, 2005, 2006)
- LIS 4020 – Professional Principles and Ethics (Summer 2000)
- LIS 4040 – Management of Libraries and Information Centers (Fall 2010; Spring 2003, 2009 (DS); Winter 2005)
- LIS 4070 – Cataloging and Classification (Winter 2008, 2009, 2010, 2011, 2012; Fall 2009 (DS))
- LIS 4321 – Collection Management (Spring 2005)
- LIS 4326 – LIS Research (Winter 2009 (DS); Spring 2009 (DS))
- LIS 4350 – Adult Materials and Services (Summer 2006, 2009)
- LIS 4379 – Social Sciences Resources (Spring 2009)
- LIS 4400 – Cataloging and Classification (Spring 2000, 2001; Winter 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009; Summer 2005, 2006 – course renumbered LIS 4070, September 2007)
- LIS 4401 – Descriptive Cataloging (Winter 2001; Spring 2002, 2003, 2006, 2007, 2008, 2009; Summer 2005)
- LIS 4402 – Subject Cataloging (Spring 2001, 2009; Summer 2005, 2006, 2007, 2008)
- LIS 4403 – Classification Schemes (Fall 2007, 2008, 2009 (DS))
- LIS 4405 – Authority Control (Winter 2009)
- LIS 4510 – Materials and Services for Children (Winter 2004; Summer 2005)
- LIS 4620 – Grant Writing and Fundraising (Summer 2000, 2002, 2004, 2010; Winter 2006; Fall 2006, 2007, 2008, 2009)
- LIS 4700 – Seminar in Technical Services (Fall 2001)
- LIS 4700 – Seminar in Public Libraries (Summer 2002)
- LIS 4804 – Management of Electronic Records (Spring 2004; Fall 2005)
- LIS 4902 – Capstone Projects (Winter 2003, Spring 2008, 2009, 2011)
- LIS 4910 – Independent Study (every quarter Winter 2000 through Spring 2011)
- LIS 4920 – Service Learning (every quarter Summer 2004 through Spring 2011)
- RMS 4954 – Grant Writing (Summer 2013, 2014)
- RMS 4959 – Content Analysis Methodology (Spring 2015)
- QRM 4978 – Grant Writing (Summer 2011, 2012)

Rutgers University, School of Communication and Information

- SC&I 522 – Cataloging and Classification (Summer 2013)

University of Arizona, College of Behavioral and Social Sciences

- LIS 602 – Cataloging and Classification (Summer 1995)
- LIS 612 – Advanced Online Search and Retrieval (Summer 1995)

Sam Houston State University, College of Education & Applied Science

- LIS 532 - Cataloging and Classification (Fall 1993, 1994, 1995)
- LIS 563 - Advanced Cataloging and Classification (Summer 1994)
- LIS 567 - Research Methods (Spring 1994, Spring 1995)
- LIS 591 - Educational Technology (Spring 1994, 1995)
- LIS 596 - Networking and Computer Technologies in Education (Fall 1993, Summer 1994, Fall 1995)

Dissertations at the University of Denver

- Bowers, Stacey L. *Library Anxiety of Law School Students: A Study Utilizing the Multidimensional Library Anxiety Scale*. Chair, May 5, 2010.
- Fattor, Melissa M. *Student Engagement Differences by Ethnicity and Scale for Ninth Grade Students*. Chair, November 1, 2010.
- Fulton, Roseanne. *A Case Study of Culturally Responsive Teaching in Middle School Mathematics*. Kent Seidel, Chair, June 18, 2009, Outside Chair.
- Grealy, Deborah S. *Tribes and Territories in Library and Information Studies Education*. Bruce Uhrmacher, Chair, June 10, 2008, Committee Member.
- McCord, J. Michael. *Developing a Standard of Care for Educational Malpractice*. Chair, April 15, 2011.
- Priebe, Sarah J. *Distinguishing Effects of Domain and General Knowledge on Passage Fluency and Comprehension*. Jan Keenan, Chair. July 21, 2011, Outside Chair.
- Snyder-Mondragon, Sandra M. *Institutional Factors that Impact the Retention of Graduate Students of Color in Schools of Library and Information Science: A Metaregression of Accredited Library School Statistics on Student Retention and Graduation Rates*. Kathy Green, Chair, July 24, 2009, Committee Member.
- Taylor, Karen Pickles. *Effective Teaching*. Elinor Katz, Chair, July 15, 2009, Outside Chair.
- Thompson, Jennifer. *Distinguishing a Western Women's College: A History of the Curriculum and Student Experience at Colorado Women's College*. Edith W. King, Chair, July 16, 2010, Committee Member.
- Walker, Emelda. *Influence of Organizational Factors on Job Satisfaction of Disability Service Providers at Postsecondary Institutions*. Chair, April 29, 2010.

Dissertation Proposals at the University of Denver

- Bowers, Stacey L. *Library Anxiety of Law School Students: A Study Utilizing the Multidimensional Library Anxiety Scale*. Chair, November 5, 2009.
- McCord, J. Michael. *Developing a Standard of Care for Educational Malpractice*. Edith W. King, Chair. April 23, 2010.
- Thompson, Jennifer. *History of Colorado Women's College*. Edith W. King, Chair, October 30, 2008. Committee Member.
- Walker, Emelda. *Influence of Organizational Factors on Job Satisfaction of Disability Service Providers at Postsecondary Institutions*. Chair, July 21, 2009.

Dissertations at Other Institutions

- Rodríguez-Mori, Howard. *The Information Behavior of Puerto Rican Immigrants to Central Florida, 2003-2009: Grounded Analysis of Six Case Studies Use of Social Networks during the Migration Process*. Kathleen Burnett, Chair, April 10, 2009, Florida State University, Committee Member.
- Schwartz, Brian *More than a Look-up Skill: Medical Information Literacy Education in Osteopathic Medical Schools*. D. Mirah Dow, Chair, July 18, 2017. Emporia State University, Committee Member.
- Snow, Karen. *A Study of the Perception of Cataloging Quality among Catalogers*. Shawne D. Miksa, Chair, August 1, 2011. University of North Texas, Committee Member.

Dissertation Proposals at Other Institutions

Schwartz, Brian *More than a Look-up Skill: Medical Information Literacy Education in Osteopathic Medical Schools*. D. Mirah Dow, Chair, December 4, 2015. Emporia State University, Committee Member.

Snow, Karen. *A Study of the Perception of Cataloging Quality among Catalogers*. Shawne D. Miksa, Chair, May 11, 2010. University of North Texas, Committee Member.

Master's Thesis at the University of Denver

Hemingson, Jeff. *Recital Paper*. Lamont School of Music, February 2010, Outside Chair.

Capstones at the University of Denver

Anthony, Alisa. *Correlation of Library and Information Science Program outcomes and Vacant Position Qualifications Listed on the Colorado State Library Jobline by Employers During the Period September 1, 2000 through August 31, 2002*. Chair, Winter Quarter, 2003.

Borden, Donna M. *Improving Emergency Communications Systems: Is a Radio Communications Network the Answer?* Fall Quarter, 2014.

Bowden, Heather L.M. *Exploring Biological Models for Long-term Data Preservation*. Chair, Spring Quarter, 2008.

Casenada, Cassandra Y. *Challenges to the Recruitment, Education, and Retention of Librarians of Color*. Chair, Spring Quarter, 2008.

Chang, Jennifer C. *Legal Research Practice and Preference: A Law Firm Perspective*. Chair, Spring Quarter 2011.

Ellis, Megan S. Fitzgerald. *Design of a Public Library Adult Volunteer Recruitment Program and Training Curriculum*. Chair, Winter Quarter, 2003.

Kircher, Kathy. *Development of a Library Pathfinder for Exobiology and Posting it on the Internet*. Chair, Winter Quarter, 2003.

Melhado, Loretta. *Design of St. John's Episcopal Church Library*. Chair, Spring Quarter, 2008.

Radcliff, Kathy. *Original Cataloging of Archival materials in the HERS Collection in Penrose Library*. Chair, Winter Quarter, 2003.

Sass, Carol Ann. *ACT Periodical Index: Access to Catholic Thinking Periodical Index: Web Index to Select Catholic Periodicals*. Spring Quarter 2000.

Stone, Sergio D. *Conducting Community Analysis for the Bemis Public Library (Littleton, Colorado) Using 2002 U.S. Census Data and the Online Outcome-Based Evaluation Toolkit*. Chair, Winter Quarter, 2003.

Tureson, Tamara. *Design and Use of an Information Audit Tool for Use in a Law Library*. Chair, Winter Quarter, 2003.

Tweed, Beth. *Evaluation of Email Reference Service in a Consumer Health Library Environment*. Chair, Winter Quarter, 2003.

GRANTS AND CONTRACTS

Student Learning in Agriculture STEM through Teacher Professional Development. Research team: Stanton Gartin (PI) and Cyndi Hofmeister, Northeast Junior College; Jeff Cash, Cheryl Sánchez, Anne-Marie Crampton, Lamar Community College; Suzanna Spears, Morgan Community College; Jack Wiley, Kerry Gabrielson, Trinidad State Junior College; Michael J. Miller, Colorado State University; Michael Womochil (Co-PI), Casey Sacks, and Sylvia D. Hall-Ellis, Colorado Community College System. U.S. Department of Agriculture, Agriculture and Food Research Initiative, Food, Agriculture, Natural Resources and Human Sciences Education and Literacy Initiative, \$404,460 (2017-2020)

Leading and Achieving: the Colorado Agriculture Regional Consortium. Research team: Jack Wiley (PI), Kerry Gabrielson, Trinidad State Junior College; Jeff Cash (PI), Cheryl Sánchez, Anne-Marie Crampton, Lamar Community College; Suzanna Spears, Morgan Community College; Cyndi Hofmeister, Northeast Junior College; Michael Womochil (Co-PI), Casey Sacks, and Sylvia D. Hall-Ellis, Colorado Community College System. U.S. Department of Agriculture, Hispanic Serving Institutions Education Grants Program, \$504,414 (2017-2020)

Cyber Prep Program Planning Grant. Research team: Debbie Sagen (PI), Brenda Lauer, Pikes Peak Community College; Gretchen Martin, Koiosa Insights; and, Sylvia D. Hall-Ellis, Colorado Community College System. U.S. Department of Commerce, Regional Alliances and Multi-stakeholder Partnerships to Stimulate (RAMPS) Cybersecurity Education and Workforce Development, \$199,681 (2016-2018)

Career and Technical Education in Colorado: Pathways to Education and Employment. Research team: Heather McKay (PI), Rutgers University; Sarah Heath, Casey Sacks, Sylvia D. Hall-Ellis, Colorado Community College System. U.S. Department of Education, Institute of Education Sciences, \$1,400,000 (2017-2021)

Pre-Alliance Planning Grant Colorado Community College Alliance. Research team: Victor Vialpondo (PI) and Janel Highfill, Community College of Aurora; Heidi Loshbaugh (Co-PI), Community College of Denver; Rick Reeves, Bill McGreevy, Liz Cox, and Kristin Aslin, Red Rocks Community College; Cathy Pellish, Front Range Community College; Samuel DeVries, Arapahoe Community College; Sylvia D. Hall-Ellis, Colorado Community College System. National Science Foundation, Louis Stokes Alliance for Minority Participation (LSAMP), \$86,817 (2016-2017)

Towards Scalable Differentiated Instruction Using Technology-enabled, Competency-based, Dynamic Scaffolding. Research team: Karen Wilcox (PI) and Vijay Kumar, Center for Computational Engineering, Massachusetts Institute of Technology; Flora McMartin, Broad-based Knowledge; Quinsigamond Community College; and, Casey Sacks, and Sylvia D. Hall-Ellis, Colorado Community College System. U.S. Department of Education, First in the World Developmental Grant, \$2,891,882 (2015-2019)

Colorado Strategic Partnerships Emergency Grant. Research team: Elise Lowe-Vaughn (PI), Amy Hodson, Celia Hardin, Barbara McBride, James Newby, Christopher Dewhurst, Nina Holland, Kate Anderson, MaryAnn Roe, Chrystalynn Chrystalynn, Elaine Edon, Mona Barnes, Tom Morgan, Rob Hanni, and Marie Valenzuela, Colorado Department of Labor and Employment; Steve Anton, Joelle Brouner, and, Katie Griego, Colorado Department of Human Services; Rebecca Holmes, Judith Martinez, and Jennifer Jirous, Colorado Department of Education; Emily Templin Lesh, Colorado Workforce Development Council; Cory Everett, Colorado Department of Regulatory Agencies; and, Casey Sacks and Sylvia D. Hall-Ellis, Colorado Community College System. U.S. Department of Labor, Strategic Partnerships Emergency Grant, \$5,000,000 (2015-2017)

CAEL Jump Start Program: Competency-Based Education. Research team: Jerry Migler (PI), Casey Sacks, Debra Cohn, Thomas Hartman, and Sylvia D. Hall-Ellis, Colorado Community College System; Matt Jamison, Front Range Community College; Mike Coste, Red Rocks Community College; Amanda Corum, Pueblo Community College; Janet Colvin, Pikes Peak Community College; and, MaryAnn Matheny, Community College of Denver. Council for Adult and Experiential Learning, \$15,000 (2015)

Summit on the Redesign of Developmental Education. Research team: Jerry Migler (PI), Casey Sacks, and Sylvia D. Hall-Ellis, Colorado Community College System; Chip Nava, Pueblo Community College; Kim Moultny,

Arapahoe Community College; Debbie Ulibarri, Trinidad State Junior College; and, Kris Bernard, Front Range Community College. American Association of Community Colleges, \$15,000 (2015-2016)

Equity in Excellence at Colorado Community Colleges. Research team: Keith Howard (PI) and Sylvia D. Hall-Ellis, Colorado Community College System; Estela Mata Bensimon, Center for Urban Education, University of Southern California; and Kerry Gabrielson, Trinidad State Junior College. Colorado Department of Higher Education, Colorado Opportunity Scholarship Program, \$150,000 (2015-2016)

MBA High School of Business in Colorado. Research team: Laurie Urich (PI) and Sylvia D. Hall-Ellis, Colorado Community College System; Rudolph Sumpter and Beatrice Gerrish, Boulder Valley Schools; Keith Curry Lance, RSL Research Group. Colorado Department of Higher Education, Colorado Opportunity Scholarship Program, \$501,295 (2015-2016)

Fullbridge Program in Colorado. Research team: Keith Howard (PI) and Sylvia D. Hall-Ellis, Colorado Community College System; Suzanna Spears, Fort Morgan Community College; and, Cheryl Sánchez and Anne-Marie Compton, Lamar Community College. Colorado Department of Higher Education, Colorado Opportunity Scholarship Program, \$300,000 (2015-2017)

Colorado Community College System Alternative Credit Program. Research team: Jerry Migler (PI), Keith Howard, and Sylvia D. Hall-Ellis, Colorado Community College System. American Council on Education, \$13,000 (2015)

Internationalization in Higher Education. Researcher: Samuel D. Museus. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Internationalization, \$8,000 (2014-2015)

International Perspectives on Bilingual Education. Researcher: Sharolyn Pollard-Durodola. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Internationalization, \$3,700 (2014-2015)

Cultivating Culturally Relevant and Responsive Curriculum and Pedagogy in College. Researcher: Samuel Museus. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, iRise Grant, \$5,000 (2014-2015)

Project EMERGE (Educational Model for Evaluation and Replicability in Gifted Environments). Research team: Norma Hafenstein (PI) and Bruce Uhrmacher. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Lynde and Harry Bradley Foundation, \$235,000 (2014-2015)

Collecting Asian American Refugee Stories. Researcher: Samuel Museus. Technical reviewer for MCE: Sylvia D. Hall-Ellis. American Educational Research Association, Research Grant, \$5,000 (2014-2015)

Developing Expertise in Teaching K-5 Mathematics. Research team: Julie Sarama (PI) and Douglas H. Clements (Co-PI), in partnership with the School of Education at the University of Michigan. Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Science Foundation, \$130,344 (2013-2015)

Investigation of the Long-Term Outcomes for Special Education Students. Researcher: Antonio Olmos-Gallos. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Jefferson County School District, Office of Assessment, \$40,000 (2014)

Refugee Community Collaboration. Researcher: Vicki Tomlin (PI) in partnership with the African Community Center and Jewish Family Service. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Center for Community Engagement and Service Learning, \$14,854 (2014-2015)

Access to Mathematics for All. Research team: Richard S. Kitchen (PI), Nicole M. Russell (Co-PI), and Terrence Blackman (Co-PI), Curriculum Studies and Teaching Program, Morgridge College of Education; Álvaro Árias (Co-PI, Department of Mathematics); and, James Gray (Co-PI), Department of Mathematics, Community

College of Aurora. Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Science Foundation, The Robert Noyce Scholarship Program, Capacity Building Project, \$349,926 (2014-2016)

Cognitive Test Battery for Intellectual Disabilities. Research team: Karen Riley (PI), Lyndsay Agans, Jessica Lerner, and Karin Dittrick-Nathan in partnership with David Hessel (PI), The MIND Institute at the University of California – Davis, and Elizabeth Berry-Kravis, Rush University Medical Center. Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Institutes of Health, Outcome Measures for Use in Treatment Trials for Individuals with Intellectual and Developmental Disabilities (R01), \$2,499,996 (\$588,672 at DU) (2014-2019)

Broadening Participation in Engineering among Women and Latino/as: A Longitudinal, Multi-Site Study. Researcher: Patton Garriott (PI) in partnership with the University of North Dakota and the University of Missouri. Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Science Foundation, HER Core Research, \$677,390 (\$69,992 at DU) (2014-2019)

Designing a Teacher Evaluation System to Improve Teacher Effectiveness for Culturally and Linguistically Diverse Learners. Research team: María del Carmen Sálazar (PI), Jessica Lerner, and Kathy Green. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Professional Research Opportunities for Faculty, \$29,988 (2014-2016)

Developing a College-Going Culture in Latina/O Families: Exploring the Influence of Funds of Knowledge on Family Outreach Programs. Researcher: Judy Marquez Kiyama. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Professional Research Opportunities for Faculty, \$18,720 (2014-2016)

Assessment of Quality of Life in Neutral Implantation Surgery for the Treatment of Parkinson's Disease. Researcher: Cynthia McRae. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Internationalization, \$3,967 (2014-2015)

Pura Vida: Cloud Forest, Curriculum and Cross-Cultural Study. Research team: Norma Hafenstein (PI) and Bruce Uhrmacher (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Internationalization, \$8,000 (2014-2015)

Online Course Development for Curriculum and Instruction. Researcher: Ruth Chao. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Teaching and Learning, \$3,000 (2014)

Online Course Development for Curriculum and Instruction. Researcher: María del Carmen Sálazar. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Teaching and Learning, \$3,000 (2014)

Online Course Development for Curriculum and Instruction. Researcher: Jessica Lerner. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Teaching and Learning, \$3,000 (2014)

Online Course Development for Curriculum and Instruction. Researcher: Duan Zhang. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Teaching and Learning, \$3,000 (2014)

The Mathematics Education of African Americans, 1866 – 1954. Researcher: Nicole M. Russell. Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Academy of Education, Spencer Foundation Postdoctoral Fellowship, \$55,000 (2014-2016)

Early Childhood Care and Education Study. Research team: Carrie Germeroth (PI), Melissa Mincic, and Douglas H. Clements. Technical reviewer for MCE: Sylvia D. Hall-Ellis. State of North Dakota, Department of Public Instruction, \$73,500 (2013-2014)

- Graduate Level Specialty in Addiction Counselor Training with Emphasis on Integration of Native American Specific Content.* Research team: Ruth Chao (PI) and Michael J. Faragher (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. The Galena Foundation, \$289,732 (2013-2016)
- The Collecting Asian American and Pacific Islander Refugee Stories (CARS) Project.* Researcher: Samuel Museus. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Center for Community Engagement and Service Learning, \$15,000 (2014)
- Parents in Transition: A Multiple Case Study of Parent and Family Orientation Programs.* Researcher: Judy Marquéz Kiyama. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Faculty Research Fund, \$1,500 (2014-2015)
- The Sistah Network: Black Women Graduate Students Supporting and Retaining Each Other.* Researcher; Nicole M. Russell. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Faculty Research Fund, \$2,708 (2014-2015)
- Evaluation of the Northeast Denver Babies Ready for College Program.* Research team: Carrie Germeroth (PI), Melissa Mincic, and Douglas H. Clements. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Mile High Montessori, \$9,922 (2013-2014)
- Developing Teaching Expertise in K-5 Mathematics.* Research team: Julie Sarama (PI) and Douglas Clements (University of Denver), in partnership with Timothy Boerst (PI), Meghan Shaughnessy, Deborah Ball, Hyman Bass (School of Education at the University of Michigan). Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Science Foundation, \$449,827 (\$130,344 at the University of Denver (2013-2015)
- Early Learning Care and Education Study Program Grant for the State of North Dakota.* Research team: Carrie Germeroth (PI), Melissa Mincic, and Sheridan Green. Technical reviewer for MCE: Sylvia D. Hall-Ellis. State of North Dakota Department of Public Instruction, \$73,500 (2013-2014)
- Local Professional Learning Community for School Leaders.* Research team: Susan Korach (PI), Kristina Hesbol, and Rebecca McClure. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Education Development Center, \$10,950 (2013)
- Healthy Eaters, Lifelong Movers 2: Implementing Evidence-Based School Environment, Policy, and Curricular Changes to Increase Opportunities for Healthy Eating and Physical Activity in Low Income, Rural Colorado.* Research team: Elaine Berlansky, University of Colorado at Denver (PI), Nicholas Cutforth, University of Denver (Co-PI), and Allison Reeds. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Health Foundation, \$3,103,108 (2013-2017)
- Hughes Rare Books Library Room Renovation in the Sturm College of Law.* Project team: Patti H. Marks, Sylvia D. Hall-Ellis, and Leigh Elliott. Mabel T. Hughes Charitable Trust, \$34,000 (2013-2014)
- The Promise Center Partnership with the Marsico Institute for Early Learning and Literacy and the City and County of Denver.* Research team: Karen Riley (PI), Douglas H. Clements (Co-PI), and Sheridan Green. Technical reviewer for MCE: Sylvia D. Hall-Ellis. The Piton Foundation, \$223,468 (2013-2014)
- Center of Excellence for Problem Gambling.* Research team: Ruth Chao (PI) and J. Mike Faragher. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Department of Behavioral Health, \$68,021 (2012-2013)
- United Way Implementation and Validation Review.* Research team: Douglas H. Clements (PI), Amanda Moreno, and Sheridan Green. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Mile High United Way, \$19,737 (2013)
- Math/Science Partnership in Rural Districts.* Research team: Kristen Bunn (PI, Eagle County Schools), Paul Michalec (Co-PI), and Alegra Reiber. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Department of Education, Colorado's Mathematics and Science Partnership Program, \$750,000 (2013-2014)

Mathematics and Science Education of African Americans. Research team: Nicole Russell (PI), Sylvia D. Hall-Ellis, Steve Fisher (Penrose Library). Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Professional Research Opportunities for Faculty, \$29,994 (2013-2015)

Online Course Development for Curriculum and Instruction. Researcher: Nicole Russell. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Teaching and Learning, \$3,000 (2013)

Discourse and Opportunity: Undocumented Students and Higher Education Policy. Researcher: Ryan Gildersleeve. Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Academy of Education, Spencer Foundation Postdoctoral Fellowship, \$55,000 (2012-2014)

An Anthropological Study of the Latino Graduation Ceremony. Researcher: Ryan Gildersleeve. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Spencer Foundation, \$39,900 (2012-2013)

Fragile-X and Pharmaceutical Company: Clinical Trial of AFQ056. University of California – Davis Children’s Hospital MIND Institute (Sacramento), Children’s Hospital Denver, and Rush Children’s Hospital at Rush University Medical Center (Chicago). Karen Riley, PI. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Novartis Pharmaceuticals Corporation, \$394,206 (2012-2014)

Project Engage, Phase 2, a DAPRA Grant in partnership with Total Immersion Systems, Inc., and Texas A&M University. Research team: Karen Riley (PI) and Lyndsay Agans (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. U.S. Department of Defense, \$60,000 (2011-2013)

International School Psychology Practicum Exchange. Researcher: Gloria L. Miller. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Center for Community Engagement and Service Learning, \$14,951 (2012-2013)

Online Course Development for Curriculum and Instruction. Research team: Bruce Uhrmacher (PI) and Norma Hafenstein (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Teaching and Learning, \$18,193 (2012-2014)

Writers in the Schools. Research team: Karen Riley (PI) and Amanda Moreno (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Humanities, \$4,965 (2012-2013)

Learning Ecosystem Validation Grant. Research team: Karen Riley (PI), Lyndsay Agans, Kent Seidel, and Shimelis Assefa. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Bill & Melinda Gates Foundation, \$315,000 (2012-2013)

Project Words of Oral Reading and Language Development (WORLD). Research team: Jorge E. Gonzalez (PI), Texas A&M University; Laura Saenz (Co-PI), University of Texas – Pan American; and, Sharolyn Pollard-Durodola (Co-PI), University of Denver. Technical reviewer for MCE: Sylvia D. Hall-Ellis. U.S. Department of Education, Institute of Education Sciences, \$53,354 (2012-2015); award \$640,718, transfer from Texas A&M University

Increasing the Efficacy of an Early Mathematics Curriculum with Scaffolding Designed to Promote Self-Regulation. Research team: Douglas H. Clements (PI) and Julie Sarama (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. U.S. Department of Education, Institute of Education Sciences, \$1,445,315 (2008-2014); award \$4,541,975, transfer from University at Buffalo, The State University of New York

Using Rule Space and Poset-based Adaptive Testing Methodologies to Identify Ability Patterns in Early Mathematics and Create a Comprehensive Mathematics Ability Test. Research team: Douglas H. Clements (PI) and Julie Sarama (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Science Foundation, \$323,791 (2010-2014); award \$1,194,944, transfer from University at Buffalo, The State University of New York

Comprehensive Postdoctoral Training in Scientific Education Research. Researcher: Julie Sarama (PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. U.S. Department of Education, Institute of Education Sciences, \$133,458 (2010-2014); award \$613,353, transfer from University at Buffalo, The State University of New York

Longitudinal Study of a Successful Scaling Up Project: Extending TRIAD. Research team: Douglas H. Clements (PI), Julie Sarama (Co-PI), and Abt Associates (Carolyn Layzer, Fatih Unlu, Laurie Bozzi, Lily Fesler, Alina Martinez, Cristofer Price, James van Orden). Technical reviewer for MCE: Sylvia D. Hall-Ellis. Institute of Education Sciences, \$384,940 (2011-2015; award \$1,250,286, transfer from University at Buffalo, The State University of New York

Early Childhood Education in the Context of Mathematics, Science, and Literacy. Research team: Julie Sarama (PI), Douglas H. Clements (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. National Science Foundation, \$990,020 (2010-2014; award \$2,285,228, transfer from University at Buffalo, The State University of New York

Early Childhood Clearinghouse Information Center Redesign. Research team: Karen Riley (PI) and Amanda Moreno (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. Office of the Lt. Governor of Colorado, \$12,000 (2012-2013)

Morgridge Rural Educational Leadership Initiative. Research team: Lyndsay Agans (PI), Linda Brookhart (Co-PI), Susan Korach, and Rebecca McClure. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Morgridge Family Foundation, \$100,000 (2012-2014)

Center of Excellence for Problem Gambling. Research team: Patrick Sherry (PI) and J. Mike Faragher. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Department of Behavioral Health, \$55,000 (2012-2013)

Intermodal Transportation Institute Research Initiatives. Researcher: Patrick Sherry. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University Transportation Centers Program, Research and Innovative Technology Administration, U.S. Department of Transportation. \$600,000 (2012-2014)

Mile High United Way Social Innovation Fund Early Literacy Initiative. Gloria L. Miller, PI, Amanda Moreano, Kim Hartnett-Edwards, and Sheridan Green. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Mile High United Way, \$89,992 (2012-2013)

International School Psychology Practicum Exchange. Researcher: Gloria L. Miller. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Center for Community Engagement and Service Learning, \$1,000 (2012-2013)

Refugee Student Art Outreach. Researcher: Karin Ditttrick-Nathan. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Faculty Research Fund, \$3,000 (2012-2013)

Resistance, Resilience, and Reciprocity: Centering the Voices of Black Doctoral Women with Faculty Aspirations. Researcher: Nicole M. Russell. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Faculty Research Fund, \$2,965 (2012-2013)

Assessing Learning through Student Notebooks. Research team: Keith Miller, Nancy Sasaki, and Kathy Green. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Professional Research Opportunities for Faculty, \$30,000 (2012-2014)

International School Psychology Practicum Exchange. Researcher: Gloria L. Miller. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Internationalization, \$2,000 (2012-2013)

ELO in Colorado. Research team: Cynthia Hazel and Duan Zhang. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Legacy Foundation, \$150,000 (2012-2013)

- Creating Online LIS Courses.* Research team: Mary C. Stansbury (PI), Shimelis Assefa, Denise Anthony, Xiao Hu, and Krystyna Matusiak. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Center for Teaching and Learning, \$15,000 (2011-2013)
- Maritime Piracy Seminar.* Researcher: Ved Nanda, The Nanda Center, Sturm College of Law. Technical reviewer for Sturm College of Law: Sylvia D. Hall-Ellis. Arsenault Family Foundation, \$15,000 (2012-2013).
- Early Childhood Librarianship: An Interdisciplinary, Experiential Learning MLIS.* Researcher: Mary C. Stansbury (PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. Laura Bush's 21st Century Librarians Program, Institute for Museums and Library Services, \$249,066 (2012-2014)
- Learning Ecosystem Planning Grant.* Research team: Karen Riley (PI), Lyndsay Agans, Kent Seidel, and Shimelis Assefa. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Bill & Melinda Gates Foundation, \$281,217 (2011-2012)
- Advanced Service Learning Practitioner Faculty Grant,* Sylvia D. Hall-Ellis, University of Denver, Center for Community Engagement and Service Learning, \$400 (2011)
- Evaluating and Enhancing the EspeciallyMe Program.* Research team: Lori D. Patton and Nicole Russell. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Center for Community Engagement and Service Learning, Public Good Fellowship Grant, \$24,780 (2012)
- Choosing Excellence: Let Every Child Bloom.* Research team: Shimelis Assefa (PI) and Mary C. Stansbury (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Center for Community Engagement and Service Learning, Public Good Grant, \$7,657 (2012)
- K-8 STEM Content Specific Professional Development to Improve Elementary Student Achievement.* Research team: Kent Seidel (PI), Nicole Russell (Co-PI), Kimberly Hartnett-Edwards, Paul Michalec, Jeff Farmer, Keith Miller, Alegra Reiber, and Nancy Sasaki. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Department of Education, Improving Teacher Quality Grant, (Title II ESEA), \$307,299 (2011-2012)
- Building a Better Principal Pipeline to Boost Student Achievement.* Researcher: Susan Korach. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Denver Public Schools; a subcontract from the Wallace Foundation Grant, \$170,000 (2011-2017)
- Center of Excellence for Problem Gambling.* Research team: J. Mike Faragher (Co-PI) and Bobbie Vollmer (PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Department of Behavioral Health, \$79,999 (2011-2012)
- An Exploration of Novice Teachers' Core Competencies: Impacts on Student Achievement, and Effectiveness of Preparation.* Research team: Kent Seidel (PI), Kathy Green (Co-PI), Kimberly Hartnett-Edwards, and Duan Zhang. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Institute of Education Sciences, Effective Teachers and Effective Teaching, \$990,987 (2012-2015)
- Project Engage, a DAPRA Grant in partnership with Total Immersion Systems, Inc., and Texas A&M University.* Research team: Karen Riley (PI) and Lyndsay Agans (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. U.S. Department of Defense, \$49,964 (2011-2014)
- User-centered Evaluation of Music Search Engines.* Researcher: Xiao Hu. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Faculty Research Fund, \$2,931 (2011-2012)
- Educational Practicum in Vietnam and China to Promote the Inclusion of Young Children with Disabilities.* Researcher: Gloria L. Miller. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Office of Internationalization, \$5,000 (2011-2012)

- Evaluation of Colorado's Enhancing Quality in Infant-Toddler (EQIT) Initiative.* Research team: Virginia R. Maloney and Amanda Moreno. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Buell Foundation, \$395,884 (2011-2013)
- Creating Engaging Environments to Teach Pre-Algebra Mathematics to Elementary Students.* Research team: Álvaro Arias, Mario López, María del Carmen Salazar, and Lyndsay Agans. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver Interdisciplinary Grant, \$60,000 (2011-2012)
- Morgridge Education Technology Accessible (META) Resource Project.* Research team: Lyndsay Agans (PI) and Shimelis Assefa (Co-PI). Technical reviewer for MCE: Sylvia D. Hall-Ellis. Morgridge Family Foundation, \$36,000 (2011)
- MCE Connect: A 21st Century Framework for Faculty Development.* Research team: Bruce Uhrmacher (PI), Shimelis Assefa (Co-PI), Lyndsay Agans (Co-PI), Kimberly Hartnett-Edwards, Norma Hafenstein, Xiao Hu, Paul Michalec (Co-PI), María del Carmen Salazar (Co-PI), and Sandra Snyder-Mondragon. Technical reviewer for MCE: Sylvia D. Hall-Ellis. University of Denver, Center for Teaching and Learning, \$22,355 (2011-2012)
- Parent Education and Parent Leadership and Advocacy.* Research team: Virginia Maloney (PI) and Amanda Moreno, Marsico Institute for Early Learning and Literacy. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Health Foundation, \$27,358 (2010-2011)
- Intentional School Culture.* Researcher: Cynthia Hazel. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Denver Public Schools, \$38,040 (2010-2011)
- Healthy Eaters, Lifelong Movers: Implementing Evidence-Based School Environment, Policy, and Curricular Changes to Increase Opportunities for Healthy Eating and Physical Activity in Low Income, Rural Colorado.* Research team: Elaine Berlansky, University of Colorado at Denver (PI), Nicholas Cutforth, University of Denver (Co-PI), and Allison Reeds. Technical reviewer for MCE: Sylvia D. Hall-Ellis. Colorado Health Foundation, \$1,683,277 (2011-2014)
- Second Life Learning Community.* Research team: Don McCubbrey (PI), Sylvia D. Hall-Ellis (Co-PI), Walter LaMendola, and Paul Novak. University of Denver, Center for Teaching and Learning, \$13,000 (2010-2011)
- Reintroducing the Value of Law Librarians to Academic and Public Librarians in Colorado through the Identification and Use of Emerging Technologies.* Research team: Sylvia D. Hall-Ellis (Co-PI), Stacey L. Bowers (PI), and Christopher Hudson, in partnership with Denver Public Library, Arapahoe Library District, and the Colorado State Supreme Court Library. University of Denver, Center for Community Engagement and Service Learning, \$5,773 (2010-11)
- Reintroducing the Value of Law Librarians to Public Librarians through the Identification and Use of Emerging Technologies and Resources.* Research team: Stacey Bowers (PI) and Sylvia D. Hall-Ellis (Co-PI). American Association of Libraries, Wolters Kluwer Law & Business Grant Program, \$2,725 (2010-2011)
- Faculty Service Learning Pod.* Research team: María del Carmen Salazar and Nicholas Cutforth (Curriculum and Instruction Program), Frank Tuitt (Higher Education Program), Cynthia Hazel and Gloria Miller (Child, Family, and School Psychology Program), and Sylvia D. Hall-Ellis (Library and Information Science Program). University of Denver, Center for Community Engagement and Service Learning, \$8,000 (2010-2011)
- Lincoln Collaborative.* Research team: Antonio Esquibel (Principal, Lincoln High School), María del Carmen Salazar (Curriculum and Instruction Program), and Sylvia D. Hall-Ellis. School Improvement Grant, Denver Public Schools, \$375,000 (2010-2012)
- Future LEADers of America: Leaders III.* Research team: Denver Public Library (Kristen Svendsen, PI), the University of Denver (Sylvia D. Hall-Ellis), the Colorado Chapter of REFORMA (Orlando Archibeque), and the Colorado Association of Libraries (Martin Garnar). Laura Bush's Recruiting Librarians for the 21st Century Program, Institute for Museums and Library Services, \$988,366 (2009-2012)

Teaching for Success in the Library Environment: LIS 4030 in Library 2.0. Research team: Deborah S. Grealy (PI) and Sylvia D. Hall-Ellis (Co-PI). University of Denver, Center for Teaching and Learning, \$ 9,350 (2009-10)

Writing Group Faculty Grant, Sylvia D. Hall-Ellis, University of Denver, Center for Community Engagement and Service Learning, \$750 (2008-2009)

Collaborative Learning Faculty Grant, Sylvia D. Hall-Ellis, University of Denver, Center for Teaching and Learning, \$1,500 (2008)

Connecting Information Literacy to Learning. Research team: Lori Micho, Merrie Valliant, Amanda Samland, and Sylvia D. Hall-Ellis. Colorado State Library, LSTA Discretionary Grant Program, \$19,548 (2008-2009)

Law Librarianship Fellows Program. Research team: Sylvia D. Hall-Ellis (PI), Stacey Bowers (Co-PI), and Christopher Hudson, Westminster Law Library. Laura Bush's 21st Century Librarians Program, Institute for Museums and Library Services, \$999,370 (2008-2012)

Grant Writing in a Cooperative Learning Environment. Sylvia D. Hall-Ellis. University of Denver, Center for Teaching and Learning, \$2,000 (2008-2009)

Project Homeless Connect 6 Event Evaluation. Research team: Sylvia D. Hall-Ellis and Duan Zhang. University of Denver Center for Community Engagement and Service Learning, \$9,785 (2008)

Project Ecuador: International Learning Service Libraries – A Faculty Development Experience in Ecuador. Sylvia D. Hall-Ellis, Office of Internationalization, University of Denver, \$600 (2007)

Project Ecuador: International Learning Service Libraries – A Faculty Development Experience in Ecuador. Sylvia D. Hall-Ellis, International Service Learning Office, University of Denver, \$400 (2007)

Project Homeless Connect 5 Event Evaluation. Research team: Sylvia D. Hall-Ellis and Duan Zhang. University of Denver Center for Community Engagement and Service Learning, \$1,000 (2007)

Project Homeless Connect 4 Event Evaluation. Research team: Sylvia D. Hall-Ellis and Duan Zhang. University of Denver Center for Community Engagement and Service Learning, \$4,595 (2007)

Future LEADers of America: Leaders II. Research team: Denver Public Library (Kristen Svendson, PI), the University of Denver (Sylvia D. Hall-Ellis), and the Colorado Chapter of REFORMA (Orlando Archibeque). Laura Bush's Recruiting Librarians for the 21st Century Program, Institute for Museums and Library Services, \$988,518 (2007-2010)

Strategic Planning Assistance for the Denver Medical Library. Sylvia D. Hall-Ellis. Denver Medical Library, Inc., \$30,000 (2006-2007)

Destiny Software for JMAC Student Lab. Sylvia D. Hall-Ellis, gift from the Sagebrush Corporation, Minneapolis, Minnesota, \$10,000 (2006)

Libraries: Tools for Education and Development Worldwide: A Faculty Development Experience in France. Sylvia D. Hall-Ellis, Office of Internationalization, University of Denver, \$800 (2005)

Denver Public Library: Opportunities for Change. Sylvia D. Hall-Ellis, Colorado Community Based Research Network, \$2,000 (2005)

Future LEADers of America. Research team: Denver Public Library (Letty Icolari and Steve Taylor, PIs), Emporia State University (Jim Agee), and the University of Denver (Sylvia D. Hall-Ellis). Recruiting Librarians for the 21st Century Program, Institute for Museums and Library Services, \$670,315 (2005-2008)

- American Association of University Professors Summer Institute Professional Development Grant.* Sylvia D. Hall-Ellis, American Association of University Professors, \$300 (2005)
- Beta Phi Mu Alumni Tea.* Sylvia D. Hall-Ellis, gift from the Office of Alumni and Parent and Relations, University of Denver, \$2,000 (2005)
- Spectrum Software for LIS Student Lab.* Sylvia D. Hall-Ellis, gift from the Sagebrush Corporation, Minneapolis, Minnesota, \$5,000 (2005)
- Developing Research Capacity in Community Organizations and Residents through Training and Technical Assistance.* Nicholas J. Cutforth (PI) and Sylvia D. Hall-Ellis. Piton Foundation, \$25,000 (2005-2006)
- Libraries: Tools for Education and Development Worldwide: A Faculty Development Experience in Argentina.* Sylvia D. Hall-Ellis, Office of Internationalization, University of Denver, \$500 (2004)
- Developing Research Capacity in Community Organizations and Residents through Training and Technical Assistance.* Research team: Nicholas J. Cutforth (PI), Gary Lichtenstein and Sylvia D. Hall-Ellis, Piton Foundation, \$25,000 (2003-2004)
- Increasing Spanish-Speaking and Hispanic Diversity among Library and Information Science Students at the University of Denver: Development of a Student Recruitment Model.* Researcher: Sylvia D. Hall-Ellis (PI), Office of Multicultural Excellence, University of Denver, \$2,750 (2003-2004)
- Collection Development Enrichment to Support the Cataloging & Classification Specialization and School Librarianship within the Library & Information Science Program at the University of Denver.* Research team: Sylvia D. Hall-Ellis (PI) and Deborah S. Grealy. Women's Library Association, University of Denver, \$4,000 (2003)
- Collection Development Enrichment to Support the Library & Information Science Program at the University of Denver.* Research team: Deborah S. Grealy (PI) and Sylvia D. Hall-Ellis. Women's Library Association, University of Denver, \$4,000 (2001)
- Wireless LAN for Library Education.* Research team: Deborah S. Grealy (PI) and Sylvia Hall-Ellis. University of Denver, Center for Teaching and Learning, \$24,000 (2001-2002)
- Upward Bound – A Program for South Texas Youth.* Research team: Monte Churchill, Executive Director of Community Relations; Gary R. Saucedo, Outreach Coordinator; Raymond Hernandez, (PI) Associate Dean for Student Success; and Sylvia D. Hall-Ellis, South Texas Community College (McAllen, Texas). U.S. Department of Education, Office of Postsecondary Education, \$2,672,003 (1999-2003)
- Write Now! Improving Elementary Students' Writing Skills.* Research team: Caryl G. Thomason, Assistant Superintendent (PI); Karen Tankersley, Principal; and, Hal Anderson, Director of Technology, Cheyenne Mountain School District 12 (Colorado Springs, Colorado); and Sylvia D. Hall-Ellis. Colorado Department of Education, Educational Telecommunications Unit, \$189,453 (1999-2001)
- Operation Quick Start -- Distance Learning in Rural Colorado.* Research team: Randal Weigum, Technology Coordinator (PI); Bonnie Barns, Director of Federal Programs and Staff Development; and, Adam "Joe" Raskop, Executive Director, Southeastern Board of Cooperative Educational Services (Lamar, Colorado); and Sylvia D. Hall-Ellis. Colorado Department of Education, Educational Telecommunications Unit, \$400,000 (1999-2001)
- Advanced Technological Training for Information Professionals for the 21st Century.* Research team: Mario Reyna, Division of Business Director (PI) and Sylvia D. Hall-Ellis, South Texas Community College (McAllen, Texas). Phi Delta Kappa and the National Science Foundation, \$250,000 (1999-2001)
- Working Connections – Training Information Technologies Professionals for the 21st Century.* Research team: Mario Reyna, Division of Business Director (PI) and Sylvia D. Hall-Ellis, South Texas Community College

(McAllen, Texas). Microsoft Corporation and the American Association of Community Colleges, \$1,147,775 (1999-2001)

The ROAD (Research Oriented Amplification of Development to Literacy) Program. Research team: Deborah J. Leong (PI), Metropolitan State University; Elena Bodrova, Metropolitan State University; Dmitri Semenov, Robert J. Marzano, and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). Hewlett-Packard Foundation, \$25,000 (1998-1999)

Press to Literacy. Research team: Deborah J. Leong (PI), Metropolitan State University; Elena Bodrova, Metropolitan State University; Dmitri Semenov, Robert J. Marzano, and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). The Denver Post and the Robert S. McCormick Foundation, \$49,818 (1998-1999)

International Telemotor Center. Research team: David Neils, David B. Frost (PI), and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). Hewlett-Packard Philanthropy, \$100,000 (1998-1999)

America Reads: Providing Tutor Training for the America Reads Challenge. Research team: Louis F. Cicchinelli (PI) and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). U.S. Department of Education, Office of Educational Research and Improvement, \$306,000 (1998-1999)

Comprehensive School Reform. Research team: Louis F. Cicchinelli (PI), J. Timothy Waters, and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). U.S. Department of Education, Office of Educational Research and Improvement, \$285,000 (1998-1999)

Sustainable Energy Education (SEE) Program for Grades 4-8: Preparing Today's Youth for Lifelong Learning and Responsible Actions in Energy Conservation. Research team: Mary Gromko, Colorado Department of Education; Gene McCarthy, Rocky Flats Field Office, U.S. Department of Energy; Gina Kissell, National Renewable Energy Laboratory; and Barbara L. McCombs (PI), Janet L. Bishop, and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). State of Colorado Governor's Office for Energy Conservation, \$499,936 (1997-1999)

Review of Kansas Curriculum Standards in Mathematics and Language Arts. Research team: Robert J. Marzano (PI), John S. Kendall, David B. Frost, and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). Submitted to the Kansas State Department of Education, \$25,903 (1998)

International Telemotor Center. Research team: David Neils, John Kuglin, Chris Rapp, David B. Frost (PI), and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). Hewlett-Packard Company, \$54,752 (1998)

Genesis Mission: Education Public Outreach. Developed in partnership by the Jet Propulsion Laboratory, California Institute of Technology, Los Alamos National Laboratory, Lockheed Martin Astronautics, and the Mid-continent Regional Educational Laboratory (Aurora, Colorado). Research team: John T. Sutton (PI), Alice Krueger, Martha Henry, Greg Rawls, Shae Isaacs, Jeff Johnson, Deb Jordan, Arlene Mitchell, David B. Frost, Jana Caldwell, J. Timothy Waters, and Sylvia D. Hall-Ellis. National Aeronautics and Space Administration, \$139,700,000; subcontract award, \$4,750,000 (1997-2007)

North Dakota Mathematics Assessment Project. Developed in partnership by the North Dakota Department of Education and Mid-continent Regional Educational Laboratory (Mid-continent Regional Educational Laboratory). Research team: Ann Clapper, Clarence Bina, Greg Gallagher, North Dakota Department of Education; Don Burger (PI), Hillary Michaels, and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). U.S. Office of Education, \$1,618,214; subcontract award, \$389,076 (1997-2001)

Pacific Resources for Education and Learning Distance Education: Project Evaluation. Developed in partnership by the Pacific Educational Community, the Pacific Resources for Education and Learning (PREL), and Mid-continent Regional Educational Laboratory (McREL). Research team: John W. Kofel (PI), Executive Director, PREL; J. Timothy Waters, Executive Director; Joan Buttram, Robert Keller, and Sylvia D. Hall-Ellis, Mid-continent Regional Educational Laboratory (Aurora, Colorado). U.S. Office of Education, Star Schools Program, \$10,000,000; subcontract award, \$500,000 (1997-2002)

Identification of Bilingual Gifted and Talented Children: A Comprehensive School Grants for Bilingual Education. Developed in partnership by Hidalgo (Texas) ISD, Los Fresnos (Texas) CISD, Progreso (Texas) ISD, University of Texas – Pan American (Edinburg, Texas), and Education Service Center, Region One (Edinburg, Texas). Research team: Hilda Medrano, Dean, College of Education, University of Texas – Pan American; Linda Phemister (PI), Janie Navarro, and Sylvia D. Hall-Ellis, Education Service Center, Region One. U.S. Department of Education, Office of Bilingual Education and Minority Languages Affairs, \$1,670,633 (1997-2002)

Academics 2000: First Things First -- The Texas Goals 2000. Developed for Jim Hogg (Hebbronville, Texas) County ISD, Mirando City (Texas) ISD, and San Isidro (Texas) ISD. Research team: Hilda Medrano, Dean, College of Education, University of Texas - Pan American (Edinburg, Texas); Angie Lehmann, Amy Mares, Ellen Gonzalez (PI), and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg, Texas). Texas Education Agency, \$339,987 (1997-2000)

Southwestern Bell's Learning Communities Initiative. Developed for Tech Prep of the Rio Grande Valley, Inc. (Harlingen, Texas); the Center for Professional Teacher Development, University of Texas – Brownsville; Teach for America – Rio Grande Valley (McAllen, Texas); and Education Service Center, Region One (Edinburg, Texas). Research team: Patricia G. Bubb, Executive Director (PI), Tech Prep of the Rio Grande Valley; Martin Winchester, Executive Director, Teach for America – Rio Grande Valley; Aileen Johnson, Director, School of Education, University of Texas – Brownsville; and Sylvia D. Hall-Ellis. Southwestern Bell Foundation, \$100,000 (1997-1998)

Texas School to Work: Regional Implementation. Developed for Tech Prep of the Rio Grande Valley, Inc. (Harlingen), South Texas Community College (McAllen), Texas State Technical College (Harlingen), Texas Southmost College (Brownsville), Empowerment Zone of the Rio Grande Valley (Mercedes), Project VIDA (Weslaco), Youth Fair Chance (McAllen), and Education Service Center, Region One (Edinburg). Research team: Patricia G. Bubb (PI), Tech Prep of the Rio Grande Valley; Stephen Vassberg, Texas State Technical College; Ellen Trevino, Youth Fair Chance; Wanda Garza, Project VIDA; Leonardo Olivares, University of Texas – Pan American; Michael Bell, South Texas Community College; and Sylvia D. Hall-Ellis. Texas Workforce Commission, \$4,250,000 (1997-2002).

Comprehensive Bilingual Education Grant for Hidalgo ISD and Roma ISD. Developed for Hidalgo (Texas) ISD, Roma (Texas) ISD, College of Education, University of Texas – Pan American (Edinburg, Texas), and Education Service Center, Region One (Edinburg, Texas). Research team: Tomas Thomas (PI), Director, Office of Bilingual Education and Sylvia D. Hall-Ellis. U.S. Department of Education, Office of Bilingual Education and Minority Languages Affairs, \$1,531,361 (1997-2002)

Lopez High School, Porter High School, Rivera High School, Central Middle School, and Perkins Middle School, Brownsville (Texas) Independent School District. Telecommunications Infrastructure Fund Board, \$1,473,611 (1997-1998)

Donna High School, Todd Middle School, and Solis Middle School, Donna (Texas) Independent School District. Telecommunications Infrastructure Fund Board, \$704,052 (1997-1998)

Memorial Middle School and Nellie Schunior Middle School, La Joya Independent School District (Texas). Telecommunications Infrastructure Fund Board, \$293,641 (1997-1998)

Martin High School, Christen Middle School, Cigarroa Middle School, Lamar Middle School, Laredo (Texas) Independent School District. Telecommunications Infrastructure Fund Board, \$1,200,000 (1997-1998).

Lasara Middle School, Lasara (Texas) Independent School District. Telecommunications Infrastructure Fund Board, \$246,210 (1997-1998)

Los Fresnos High School and Resaca Middle School, Los Fresnos (Texas) Consolidated Independent School District. Telecommunications Infrastructure Fund Board, \$500,000 (1997-1998)

Lyford Junior High School, Lyford (Texas) Independent School District. Telecommunications Infrastructure Fund Board, \$354,997 (1997-1998)

Travis Middle School, McAllen (Texas) Independent School District. Telecommunications Infrastructure Fund Board, \$269,139 (1997-1998)

Mission High School, Mission (Texas) Independent School District. Telecommunications Infrastructure Fund Board, \$297,010 (1997-1998)

Progreso High School, Progreso (Texas) Independent School District. Telecommunications Infrastructure Fund Board, \$300,000 (1997-1998)

San Perlita High School, San Perlita (Texas) Independent School District. Telecommunications Infrastructure Fund Board, \$293,490 (1997-1998)

Myra Green Junior High School, Raymondville (Texas) Independent School District. Telecommunications Infrastructure Fund Board, \$225,000 (1997-1998)

Rio Grande City High School, Ringgold Middle School, Gruella Middle School, Rio Grande City (Texas) Independent School District. Telecommunications Infrastructure Fund Board, \$809,934 (1997-1998)

Rio Hondo Junior High School, Rio Hondo (Texas) Independent School District. Telecommunications Infrastructure Fund Board, \$297,024 (1997-1998)

Roma High School, Roma (Texas) Independent School District. Telecommunications Infrastructure Fund Board, \$333,178 (1997-1998)

San Benito High School, Miller Jordan Junior High School, San Benito (Texas) Consolidated Independent School District. Telecommunications Infrastructure Fund Board, \$547,000 (1997-1998)

Santa Maria High School and Santa Maria Middle School, Santa Maria (Texas) Independent School District. Telecommunications Infrastructure Fund Board, \$400,000 (1997-1998)

Salvador High School, United Independent School District (Laredo, Texas). Telecommunications Infrastructure Fund Board, \$250,879 (1997-1998)

Weslaco High School, Cabaza Middle School, Cuellar Middle School, Weslaco (Texas) Independent School District. Telecommunications Infrastructure Fund Board, \$874,242 (1997-1998)

Principals' Assessment and Training Center. Developed for Education Service Center, Region One (Edinburg, Texas). Research team: Roberto Zamora, Leonel Barrera, William H. Parry, and Sylvia D. Hall-Ellis. Texas Principals' Leadership Initiative, Texas Association of Secondary School Principals, Texas Association of Elementary School Principals, and the Sid Richardson Foundation. \$461,439 (1996-1998)

The Texas Library Connection -- Integrating and Sharing Resources. Developed for Hidalgo County Library System (McAllen), Cameron County Library System (Brownsville), South Texas Community College (McAllen), the

University of Texas - Pan American (Edinburg), University of Texas – Brownsville, and Education Service Center, Region One (Edinburg). Research team: William R. McGee, Coordinator, Hidalgo County Library System; Joe Garcia, Director, Cameron County Library System; Michael D. Bell, Library Director, South Texas Community College; Eleanor Folger Foster, University Library, University of Texas - Pan American; Jaime Vela (PI), Director of Instructional Technology and Media Services, Ron Pontius, Instructional Technology, and Fabiola Fuentes, Media Services, Education Service Center, Region One; and Sylvia D. Hall-Ellis. Office of Library Media Services, Technology Services, Texas Education Agency. \$8,000 (1996-1997)

Developing Leadership Communities for Improving Algebra I for All Students. Developed for a partnership of the Region One Statewide Systemic Initiative Team. Research team: Noel Villarreal (PI), Eduardo Cancino, and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). Texas Statewide Systemic Initiative for Reform in Mathematics, Science and Technology Education to The Charles A. Dana Center for Mathematics and Science Education, The University of Texas at Austin. \$25,000 (1996-1997)

Academics 2000: First Things First -- The Texas Goals 2000. Developed for Edinburg (Texas) CISD. Research team: Hilda Medrano, Dean, College of Education, University of Texas - Pan American (Edinburg); Helen Jones, Director (PI), Gifted and Talented Education, Edinburg CISD; and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). Texas Education Agency, \$750,000 (1996-2001)

Texas Teachers Empowered for Achievement in Mathematics (TEXTEAM) Institute for Algebra I. Developed for Hidalgo ISD, Jim Hogg (Hebbronville) County ISD, La Joya ISD, La Villa ISD, Lyford ISD, Mission CISD, Pharr-San Juan-Alamo ISD, Rio Hondo ISD, San Isidro ISD, San Perlita ISD, Santa Maria ISD, Santa Rosa, Sharyland ISD, Valley View ISD, Webb (Laredo) CISD, Weslaco ISD, and Zapata County (Zapata) ISD. Research team: Noel Villarreal (PI), Chuck McInteer, Ellen M. Gonzalez, Education Service Center, Region One (Edinburg); and Sylvia D. Hall-Ellis. Charles A. Dana Center for Mathematics and Science Education, University of Texas - Austin, \$15,975 (1996)

Community Learning Center for La Villa, Texas. Developed for Edcouch-Elsa Independent School District. Research team: Noe Gonzalez (PI), Assistant Superintendent, Edcouch-Elsa Independent School District, and Sylvia D. Hall-Ellis. Delta Region Subzone, Rio Grande Valley (Texas) Rural Empowerment Zone, \$325,000 (1996-1997)

Monte Alto (Texas) Community Learning Center. Developed for Monte Alto Independent School District. Research team: Homero A. Diaz (PI), Superintendent, Monte Alto Independent School District, and Sylvia D. Hall-Ellis. Delta Region Subzone, Rio Grande Valley (Texas) Rural Empowerment Zone, \$300,000 (1996-1997)

Community Learning Center for La Villa, Texas. Developed for La Villa Independent School District. Research team: Sam Gonzalez (PI), Assistant Superintendent, La Villa Independent School District; and Sylvia D. Hall-Ellis. Delta Region Subzone, Rio Grande Valley (Texas) Rural Empowerment Zone, \$325,000 (1996-1997)

Building Project for Taylor Elementary. Developed for Mercedes (Texas) Independent School District. Research team: Mrs. Denise Rivera, Librarian, and Eduardo Infante, Principal, Taylor Elementary School; Ismael S. Cantu (PI), Federal Programs Director, Mercedes Independent School District; and Sylvia D. Hall-Ellis. Delta Region Subzone, Rio Grande Valley (Texas) Rural Empowerment Zone, \$375,000 (1996-1997)

Border Education Network (BEN) - Distance Education through Cable Television. Developed for Edinburg (Texas) Consolidated Independent School District. Research team: Noe Torres (PI), Library Media Specialist, Magdalena Rosas, Library Media and Technology Coordinator, Edinburg Consolidated Independent School District; and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). Edinburg (Texas) Consolidated School District, \$250,000 (1996-1997)

Multiservice One-Stop Open Enrollment Charter School. Developed for the Information Referral Resource Assistance, Inc. (McAllen, Texas). Research team: Pablo Perez and Aguié Pena (PI), Executive Director, Information Referral Resource Assistance, Inc.; Roberto Zamora and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). Texas Education Agency, \$3,066,000 (1996-2001)

- Project OK: A Community Youth Opportunities Grant for Summer, 1996.* Developed for McAllen (Texas) Independent School District, St. Joseph the Worker Catholic Church, and the Office of Adult Education, Education Service Center, Region One. Research team: Father Bart Flatt, St. Joseph the Worker Catholic Church; Noe Calvillo (PI), Office of Adult Education; Maria Louisa Garcia, McAllen Independent School District; and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). Texas Protective and Regulatory Agency through the Office of the Mayor, City of McAllen, \$350,000 (1996-2001).
- Early Childhood: a Time of Discovery.* Developed for a partnership of Lasara ISD, Rio Hondo ISD, San Perlita ISD, the School of Education, University of Texas - Brownsville, and Education Service Center, Region One (Edinburg). Research team: Hugo Rodriguez, Dean, School of Education, University of Texas - Pan American; Leonel Barrera and Jack Damron, Field Service Agents, Ellen M. Gonzalez (PI), Administrator for Student Instructional Services, Ruth Solis, Education Specialist in Special Education, and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). Texas Education Agency, \$722,090 (1996-2001)
- Innovative Gifted and Talented Programs for Early Childhood and Elementary Education Students.* Developed for a partnership of Edinburg (Texas) CISD, the School of Education, University of Texas - Pan American (Edinburg), and Education Service Center, Region One (Edinburg). Research team: Hilda Medrano, Dean, School of Education, University of Texas - Pan American; Helen de la Garza (PI), Director of Elementary Curriculum and Instruction, Edinburg CISD; and Sylvia D. Hall-Ellis. Texas Education Agency, \$750,000 (1996-2001)
- Reading Recovery in Early Elementary Grades.* Developed for a partnership of La Villa (Texas) ISD the School of Education, University of Texas - Pan American (Edinburg), and Education Service Center, Region One (Edinburg). Research team: Hilda Medrano, Dean, School of Education, University of Texas - Pan American; Marcario Salinas (PI), Supervisor of Elementary Curriculum and Instruction, La Villa ISD; and Sylvia D. Hall-Ellis, Education Service Center, Region One. Texas Education Agency, \$750,000 (1996-2001)
- Connected Mathematics Project for Middle and Junior High Students.* Developed for a partnership of Michigan State University, The Charles A. Dana Center for Mathematics and Science Education, The University of Texas at Austin and Region One Statewide Systemic Initiative Team. Research team: Jack Damron, Chuck McInteer, Noel Villarreal (PI), and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). National Science Foundation through Michigan State University to the Charles A. Dana Center at the University of Texas - Austin, \$539,610 (1996-1999)
- Sharing Resources: Testing the Interlibrary Loan Potential of the Texas Library Connection -- Integrating Media Resources.* Developed under the sponsorship of the Hidalgo County Library System (McAllen) and Education Service Center, Region One (Edinburg). Research team: William H. McGee, Hidalgo County System Coordinator; Fabiola Fuentes, Library Media; Ronald Pontius (PI), Instructional Technology, Education Service Center, Region One; and Sylvia D. Hall-Ellis. Library Media Services Program, Office of Technology Services, Texas Education Agency, \$25,000 (1996-1997)
- State and Federal Adult Education JOBS Program.* Developed for Education Service Center, Region One (Edinburg). Research team: Noe Calvillo (PI), Director, Adult Education Program, and Sylvia D. Hall-Ellis. Adult Education Program, Texas Education Agency, \$532,846 (1995-1996)
- Creating Safe and Drug-Free Schools and Communities.* Developed for a partnership of the Region One Consortium for Safe and Drug-Free Education Environments. Research team: Clara Contreras (PI), Health Specialist, and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). Texas Education Agency, \$150,000 (1995-1996)
- Developing Leadership Communities for Improving Mathematics Performance for All Students on Title I Campuses.* Developed for a partnership of the Region One Statewide Systemic Initiative Team. Research team: Jack Damron, Chuck McInteer, Noel Villarreal (PI), and Sylvia D. Hall-Ellis, Education Service Center, Region One (Edinburg). Texas Statewide Systemic Initiative for Reform in Mathematics, Science and Technology Education to The Charles A. Dana Center for Mathematics and Science Education, The University of Texas at Austin, \$50,669 (1995-1996)

The Impact of Library Resource Centers on Academic Achievement in Selected Public Schools in South Texas.

Sylvia D. Hall-Ellis (PI). Developed under the sponsorship of the Department of Library Science, College of Education and Applied Science, Sam Houston State University (Huntsville). Texas Association of School Librarians, Children's Services Round Table, and Young Adults Round Table (Austin, Texas), \$2,500 (1995)

School Library Media Specialists Fellowship Program. Sylvia D. Hall-Ellis (PI). Developed under the sponsorship of the Department of Library Science, College of Education and Applied Science, Sam Houston State University (Huntsville, Texas). U.S. Department of Education, HEA Title II-B, Library Education and Human Resource Development Program, \$44,000 (1995-1996)

Planning for Educational Technology. Research team: Ruth Ann Riggins (PI), Director of Library Media and Technology Services, Donna (Texas) Independent School District; Noe Torres, Education Service Center, Region One; Patricia G. Bubbs, Tech Prep of the Rio Grande Calley, Inc; Michael D. Bell, South Texas Community College; and Sylvia D. Hall-Ellis, Sam Houston State University. Developed under the sponsorship of Donna (Texas) Independent School District, Education Service Center, Region One (Edinburg), Tech Prep of the Rio Grande Valley, Inc. (Harlingen), South Texas Community College (McAllen), and the Department of Library Science, Sam Houston State University (Huntsville). Funded through Infusion of Educational Technology Planning Grant Program (H.B. 18: Models). Texas Education Agency, \$18,000 (1993-1994)

The Impact of Library Resource Centers on Academic Achievement in Selected Public Schools in South Texas.

Sylvia D. Hall-Ellis (PI) and Mary Ann Berry. Developed under the sponsorship of the Department of Library Science, College of Education and Applied Science, Sam Houston State University (Huntsville). Sam Houston State University Research Enhancement Fund, \$7,500 (1993-1994)

Electronic Mail Resource Sharing System: Management and Operation of the Iowa Computer-Assisted Network. State Library of Iowa, \$294,000 (1986-1993)

The Iowa Locator: A CD-ROM Resource Sharing Tool. State Library of Iowa, \$567,000 (1986-1992)

Statewide Database Development: An OCLC Tape Analysis To Determine Feasibility. State Library of South Dakota, \$15,000 (1987)

The Iowa Locator: A Feasibility Study. State Library of Iowa, \$50,000 (1986)

Electronic Mail Resource Sharing System: A Feasibility Study for Libraries in the State of Iowa. State Library of Iowa, \$5,000 (1985)

Access Pennsylvania: A Feasibility Study. State Library of Pennsylvania, \$50,000 (1984)

Automating Library Administrative and Management Tasks: Procurement and Distribution of Microcomputer Systems for District Library Centers in the Commonwealth of Pennsylvania. State Library of Pennsylvania, \$495,000 (1982)

Sharing Serial Titles Resources: Procurement and Distribution of Microfiche Readers for 550 Libraries in the Commonwealth of Pennsylvania. State Library of Pennsylvania, \$500,000 (1982)

Electronic Mail System: A Pilot Project for Libraries throughout the Commonwealth of Pennsylvania. State Library of Pennsylvania, \$125,000 (1982)

Literacy Program for Adults in Rural Upstate New York State: Program Outreach and Evaluation - Phase 3. Appalachian Regional Commission, \$50,000 (1981)

Database Building: A Cooperative Project of the Finger Lakes Library System (Ithaca), Four County Library System (Binghamton), and the Southern Tier Library System (Corning). New York State Library, \$450,000 (1980-1985)

Faces of the Southern Tier: A Professional Photographer-in-Residence. New York State National Endowment for the Humanities, \$25,000 (1980)

Literacy Program for Adults in Rural Upstate New York State: Program Implementation - Phase 2. Appalachian Regional Commission, \$50,000 (1980)

Small Business Resources Center: A Pilot Project for Rural Public Libraries. New York State Library, \$50,000 (1980)

Media Programming: A Professional Development Program for Public Librarians in Upstate New York: A Program in Allegheny, Chemung, Schuylers, Steuben, and Yates Counties. New York State Library, \$35,000 (1979)

Information and Library Resources for Inmates and Prisoners in Selected Upstate New York Facilities: A Cooperative Program in Allegheny, Chemung, Schuylers, Steuben, and Yates Counties. New York State Library, \$25,000 (1979)

Library Resources for Homebound Adults in Upstate New York: An Outreach Program in Allegheny, Chemung, Schuylers, Steuben, and Yates Counties. New York State Library, \$40,000 (1979)

Literacy Program for Adults in Rural Upstate New York State: Program Initiation and Establishment - Phase 1. Funded by the Appalachian Regional Commission. Awarded to the Corning (New York) Public Library, \$50,000 (1979)

Information Reference Services to Homebound Adults. New York State Library, \$31,000 (1978)

Books-By-Mail Services to Homebound Adults. New York State Library, \$31,000 (1978)

System Headquarters Services and Programs for Public Libraries in District 10. Funded through Library Services and Construction Act Title I. Texas State Library and Historical Commission, \$880,000 (1976)

County Library Development Grant for Atascosita County. Funded through Library Services and Construction Act Title I. Texas State Library and Historical Commission, \$15,000 (1976)

Spanish Language Materials Collection Development Program. Texas State Library and Historical Commission, \$40,000 (1975)

Establishment of System Headquarters for Alamo Regional Library System (District 10) Headquartered at the San Antonio (Texas) Public Library. Texas State Library and Historical Commission, \$800,000 (1975)

SELECTED CONSULTANTSHIPS

Project Strategic Planning & Funding Proposal Development

Walden University, 2015.

Pikes Peak Library District, 2014.

Douglas County Public Libraries, 2011-2012.

Denver School for Science and Technology, 2008-2011.

Johnson & Wales University, Denver Campus, 2007-2009.

Challenges, Choices, and Images K-12 Charter School, Denver Public Schools, 2007.

Denver Medical Library, Inc., 2006-2010.

Bemis Public Library (Littleton), Ergonomic Design and Facilities Enhancement Consultant, 2003.

Curtis Park Community Center (Denver), Community Technology Center Evaluation and Proposal Development Consultant, 2003.

Colorado Community Based Research Network (Denver), Funding Research Associate, 2002-

Our Lady of the Rosary Academy (Edgewater), Learning Resource Center Development Project Consultant, 2001-

University of Southern Colorado (Pueblo). Technology Integration and Curriculum Enhancement into Higher Education Learning Environment. Proposal Development Consultant, 2000.

Jefferson County Library System (Lakewood), 1999-2000.

Southeastern BOCES (Lamar, CO). Distance Learning Curriculum Content Development Project. Proposal Development Consultant, 1998-2004.

Cheyenne Mountain School District 12 (Colorado Springs, CO). Technology Integration into Elementary Writing Curriculum Project. Proposal Development Consultant, 1998.

Telecommunications Infrastructure Fund Board Round #2 Application, 1997. Technical assistance to the following: La Villa (Texas) Independent School District; Mirando City (Texas) Independent School District; Monte Alto (Texas) Independent School District; San Isidro (Texas) Independent School District.

Telecommunications Infrastructure Fund Board Round #1, 1996. Technical assistance to the following: Brownsville (Texas) Independent School District; Donna (Texas) Independent School District; Edinburg (Texas) Consolidated Independent School District; Harlingen (Texas) Consolidated Independent School District; Jim Hogg County Independent School District (Hebbronville, Texas); La Feria (Texas) Independent School District; La Joya (Texas) Independent School District; La Villa (Texas) Independent School District; Los Fresnos (Texas) Consolidated Independent School District; Progreso (Texas) Independent School District; Raymondville (Texas) Independent School District; Rio Hondo (Texas) Independent School District; San Benito (Texas) Independent School District; Sharyland Independent School District (Mission, Texas); Weslaco (Texas) Independent School District; Zapata (Texas) County Independent School District.

South Texas Community College (McAllen). Strategy Development to Meet the Technology Instructional Needs for Vocational, School-To-Work and Academic Programs, 1994-2000. Development Consultant.

Donna (Texas) Independent School District. Planning for the Infusion of Technology in Middle Schools Serving High At-Risk Students, 1994-1995. Research Associate.

Pettus (Texas) Independent School District. Planning for District-wide Automation in School Library Media Centers: Preparation of Data, and CD-ROM Hardware/Software Configuration Evaluation, 1994. Principal Investigator.

Fort Bend Independent School District (Sugar Land, TX). Planning for District-wide Automation in School Library Media Centers, Preparation of Data, and CD-ROM Hardware/Software Configuration Evaluation, 1994-1995. Principal Investigator.

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EXHIBIT B

Neue Therapieoptionen in der Behandlung der pulmonalarteriellen Hypertonie

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Zusammenfassung

Trotz aller Fortschritte in der Therapie der pulmonalarteriellen Hypertonie gibt es bisher keine Aussicht auf Heilung dieser schwerwiegenden Erkrankung. Mit der Einführung effektiver und nonparenteraler Medikamente (z.B. orale Endothelin-Rezeptor-Antagonisten [ERA], inhalative Prostanoiden) haben sich jedoch die Lebensqualität, die körperliche Belastbarkeit und die Prognose der Patienten in den letzten Jahren erheblich verbessern lassen. Die Anwendbarkeit dieser Medikamente ist aber durch die z.T. gravierenden Nebenwirkungen und/oder aufwendigen Applikationsformen eingeschränkt. Ob selektive ERA aufgrund ihrer Spezifität für den A-Rezeptor Vorteile gegenüber dem nichtselektiven ERA Bosentan im Hinblick auf Nebenwirkungen, aber auch in Bezug auf die Effektivität haben, wird erst nach Auswertung der derzeit laufenden zulassungsrelevanten Studien mit Ambrisentan und Sitaxsentan zu eruieren sein. Inhaliertes Treprostinil könnte aufgrund seiner hohen Selektivität für die pulmonale Zirkulation sowie auf-

grund der längeren Wirkung einen Vorteil gegenüber dem bereits zugelassenen inhalierten Iloprost haben. Bisher stehen jedoch noch Ergebnisse einer kontrollierten randomisierten Studie aus, die die Wirksamkeit dieser Therapie in der chronischen Anwendung dokumentieren. Der selektive Phosphodiesterase-5-(PDE5-)Inhibitor Sildenafil ist im Vergleich zu den vorgenannten Substanzen bereits am nächsten zur klinischen Zulassung. Sildenafil erwies sich bei verschiedenen Formen der pulmonalen Hypertonie als starker pulmonal selektiver Vasodilatator. Die Ergebnisse der Phase-III-Studie zur Anwendung von Sildenafil bei pulmonalarterieller Hypertonie bestätigen die hervorragende Wirksamkeit dieses Medikaments bei exzellenter Verträglichkeit. Kombinationstherapien stellen bei allen noch zu erwartenden Fortschritten in der Entwicklung einzelner Substanzen die aussichtsreichste zukünftige Therapieoption dar. Kontrollierte Studien zur Überprüfung dieser Option, unter Berücksichtigung verschiedener Medikamentenkombinationen, befinden sich bereits in Planung.

Schlüsselwörter: Pulmonale Hypertonie · Vasodilatative Therapie · Stickstoffmonoxid · Prostacyclin · Endothelinantagonist · Phosphodiesteraseinhibitoren · Kombinationstherapien

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Emerging Therapies for the Treatment of Pulmonary Arterial Hypertension

Abstract

Besides all progress in the therapy of pulmonary arterial hypertension over the past years, there is still no cure for this devastating disease. By introducing effective and nonparenteral medications (e.g., oral endothelin receptor antagonists [ERAs], inhaled prostanoids), quality of life, exercise tolerance and prognosis of patients have substantially improved. However, applicability of these therapies can be hampered by serious side effects and/or the necessity for elaborate application techniques. Whether selective ERAs – due to their specificity for the A-type receptor – have potential benefits over the nonselective ERA bosentan remains to be answered by

the analysis of pivotal trials recently carried out with ambrisentan and sitaxsentan. Inhaled treprostinil can potentially have benefits over the already approved inhaled iloprost, related to its higher pulmonary selectivity as well as to the longer biological half-life. However, this has yet to be proven in long-term randomized controlled trials. In comparison to the previously mentioned substances, the selective phosphodiesterase-5 (PDE5) inhibitor sildenafil approached approval closest as new therapy for pulmonary arterial hypertension. Oral sildenafil has proven its efficacy as a selective pulmonary vasodilator in various forms of pulmonary hypertension. The results of the pivotal phase III trial have confirmed the

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strong efficacy and excellent tolerability of this substance. Combination therapies, despite all progress seen for single agents, can be regarded as the most promising therapeutic

approach for the future. However, controlled randomized trials that are currently under consideration have to confirm this notion.

Key Words: Pulmonary hypertension · Vasodilative therapy · Nitric oxide · Prostacyclin · Endothelin antagonist · Phosphodiesterase inhibitors · Combination therapies

Einleitung

Im Beitrag von Hoepfer in diesem Heft wurde bereits ausführlich auf die leitliniengerechte Therapie der pulmonalarteriellen Hypertonie (PAH) eingegangen. Leitliniengerecht bedeutet in diesem Fall die Bezugnahme auf zugelassene Medikamente oder Substanzen, die aufgrund einer eindeutigen Publikationslage Eingang in die evidenzbasierten Therapieempfehlungen gefunden haben. Inhalt dieses Beitrags wird die Darstellung neuer, z.T. noch in Entwicklung befindlicher Therapieansätze sein, die in naher Zukunft Eingang in die Therapieleitlinien finden können oder die bereits aufgrund eines eindeutigen Wirksamkeitsnachweises im sog. „off-label use“ zum Einsatz kommen. Im Einzelnen werden wir auf die Therapie mit inhalierten Prostanoiden, selektiven Endothelin-A-Rezeptor-Antagonisten (Sitaxsentan und Ambrisentan) sowie Phosphodiesterase-5-(PDE5-)Hemmern (hier insbesondere Sildenafil) eingehen. Des Weiteren werden Kombinationstherapien als möglicher zukünftiger Therapiestandard diskutiert.

Vasoaktive Therapie

Angriffspunkte einer vasoaktiven Therapie sind die potentiell reversiblen Komponenten der Gefäßobstruktion. Prinzipiell bestehen zwei Möglichkeiten, durch pharmakologische Intervention den Gefäßquerschnitt zu erweitern:

- Aufhebung eines dauerhaft erhöhten Vasotonus durch Relaxation der glatten Gefäßmuskulatur (unmittelbarer Effekt von Vasodilatoren);
- Beeinflussung des strukturellen Gefäßumbaus (vasculäres Remodeling) durch Nutzung von antiinflammatorischen und antiproliferativen Wirkstoffen.

Eine Vielzahl vasodilatativer Agenzien ist in der Behandlung der chronischen pulmonalen Hypertonie klinisch getestet worden. Bezüglich der Anwendung von Calciumantagonisten, Prostanoiden und nichtselektiven Endothelinantagonisten sei nochmals auf den Artikel von Hoepfer in diesem Heft hingewiesen. Obwohl in

dem genannten Artikel auch schon auf inhaliertes Iloprost (Ventavis®) eingegangen wurde, sei diese Therapieform hier noch einmal kurz erwähnt, da sie zur Erläuterung der neuen Therapie mit inhaliertem Treprostinil den theoretischen und klinischen Hintergrund liefert.

Inhalatives Iloprost

Die Inhalation aerosolierter Prostanoiden umgeht wirkungsvoll einen Großteil der Nachteile der Infusionstherapie: Durch die alveoläre Deposition des Wirkstoffs wird eine pulmonal und intrapulmonal selektive Wirkung erzielt. Die Therapie der pulmonalen Hypertonie mit wiederholten Inhalationen des lang wirksamen Prostacyclinanalogons Iloprost hat in einer multizentrischen, randomisierten, plazebokontrollierten Studie ihre Effektivität bei gleichzeitig guter Sicherheit bewiesen [1]. In der mit Iloprost behandelten Gruppe zeigte sich sowohl eine signifikante Verbesserung der 6-min-Gehstrecke (als Maßstab der Belastbarkeit) als auch der NYHA-Klasse (New York Heart Association) im Vergleich zur plazebobehandelten Gruppe. Dieser zulassungsrelevanten Studie waren bereits mehrere, nicht kontrollierte Studien an Patienten mit verschiedenen Formen der pulmonalen Hypertonie vorausgegangen [2–4]. Im Wesentlichen konnte die Phase-III-Studie hierbei die früheren positiven Erfahrungen bestätigen. Nachteile dieser Therapie sind jedoch neben der aufwendigen Aerosoltechnologie die relativ kurze Wirkdauer der einzelnen Gabe (60–90 min) mit der Notwendigkeit häufiger Inhalationen (sechs- bis neunmal täglich) und die therapeutische Pause während der Nacht.

Inhaliertes Treprostinil

Treprostinil ist ein lang wirksames Prostacyclinanalogon, welches aufgrund seiner langen Plasmahalbwertszeit und chemischen Stabilität in Lösung potentielle Vorteile gegenüber Epoprostenol bietet und somit zunächst als Substitut für die Infusionsbehandlung entwickelt wurde. Zur Vermeidung katheterassoziierter

Komplikationen wird die Treprostinilinfusion subkutan über eine (der Insulindauertherapie entnommene) Spezialkanüle infundiert. Die zulassungsrelevante Studie zu diesem Therapieprinzip hat eine Wirksamkeit bei der Behandlung von Patienten mit PAH erbracht [5]. Nachteil dieser Behandlungsform ist jedoch, dass es bei bis zu 80% der Patienten zu Schmerzen an der Injektionsstelle kommt, welche eine dauerhafte Therapie erschweren. Erste Untersuchungen aus Gießen haben den Wirksamkeitsnachweis von *inhaliertem* Treprostinil zur effektiven Senkung des pulmonalen Gefäßwiderstands (PVR) erbracht [6]. In dieser ersten Untersuchung wurde bei 17 Patienten mit schwerer präkapillärer pulmonaler Hypertonie inhaliertes Treprostinil (15 µg/Inhalation) verabreicht. Dies führte zu einer starken pulmonal selektiven Druck- und Widerstandsenkung mit einer Gesamtwirkdauer von > 180 min. Im direkten Vergleich mit inhaliertem Iloprost zeigte inhaliertes Treprostinil eine stärkere pulmonale Selektivität, so dass eine Dosissteigerung auf bis zu 90 µg (absolute inhalierte Dosis pro Inhalationsmanöver), ohne Auftreten von unerwünschten Wirkungen, möglich ist [6]. Aufgrund dieser einzigartigen Eigenschaften (ausgeprägte pulmonale Selektivität und lange Wirkdauer nach einzelner Inhalation) ist es möglich, die Anzahl notwendiger Inhalationen auf bis zu vier pro Tag zu reduzieren; die Inhalationsdauer lässt sich bei geeigneter Geräteauswahl auf < 1 min senken. Erste Daten zeigen zudem, dass eine Anwendung in nur ein bis zwei Atemzügen technisch realisierbar sein wird. Eine multizentrische, plazebokontrollierte Studie soll nun die Wirksamkeit dieser neuen Therapie auch in der Langzeitanwendung untersuchen.

Selektive Endothelin-A-Rezeptor-Antagonisten

Die Aktivierung von Endothelin-A-(ET_A-)Rezeptoren führt zur Vasokonstriktion und Gefäßproliferation in der Lunge, während der ET_B-Rezeptor zirkulierendes Endothelin bindet (und eliminiert) und zu einer Steigerung der endogenen Prostacyclin- und Stickstoffmonoxid-(NO-)Produktion führt. Außerdem wird angenommen, dass die für Bosentan beschriebene Lebertoxizität vornehmlich mit der ET_B-hemmenden Wirkung im Zusammenhang steht. Vor dem Hintergrund dieser vermutlich nachteiligen Teilkomponente des nichtselektiven Endothelin-Rezeptor-Antagonisten (ERA) sind selektive ET_A-Antagonisten in die klinische Erprobung gekommen. Hierzu liegen aktuell Erfahrungen für zwei Substanzen vor, die im Einzelnen aufgeführt sind.

Sitaxsentan. Der selektive ET_A-Rezeptor-Antagonist Sitaxsentan (Thelin®) hat eine vielfach höhere Bindungsaffinität für den ET_A- als den ET_B-Rezeptor. Präklinische Daten haben bereits auf eine mögliche Wirksamkeit zur Behandlung der PAH hingewiesen. Publierte klinische Phase-II-Daten zeigen, dass bei vergleichbarer Wirksamkeit mit Bosentan die Inzidenz von Lebertoxizität in der mit 100 mg Sitaxsentan (einmal tägliche Tabletteneinnahme) behandelten Gruppe bei 0% und in der mit 300 mg behandelten bei 10% lag [7]. Bei der derzeit noch in Auswertung befindlichen zulassungsrelevanten Phase-III-Studie kamen sowohl 50 mg als auch 100 mg Sitaxsentan im Vergleich zu Plazebo oder Bosentan (125 mg zweimal täglich) zum Einsatz. Die zurzeit nur per Pressemitteilung veröffentlichten Daten signalisieren, dass erneut die 100-mg-Dosis von Sitaxsentan bei vergleichbarer Wirksamkeit (Verbesserung der Gehstrecke im 6-min-Gehtest um 31,4 m [Sitaxsentan] vs. 29,5 m [Bosentan]) im Trend weniger Lebertoxizität aufwies als Bosentan (3% vs. 11%). Wann und für welches Patientenkollektiv es zu einer Zulassung dieser Medikation kommen wird, ist derzeit nicht bekannt. Für Sitaxsentan ist eine Interaktion mit Warfarin vorbeschrieben, die eine Dosisanpassung des oralen Antikoagulans erfordert.

Ambrisentan. Ebenso wie Sitaxsentan handelt es sich bei Ambrisentan um einen selektiven ET_A-Antagonisten [8]. Eine Phase-II-Studie zu dieser Substanz ist bereits abgeschlossen, jedoch liegen die Ergebnisse zurzeit nicht in publizierter Form vor. Die zulassungsrelevante Phase-III-Studie rekrutiert derzeit noch Patienten und wird voraussichtlich Ende 2005 zum Abschluss kommen.

Phosphodiesteraseinhibitoren

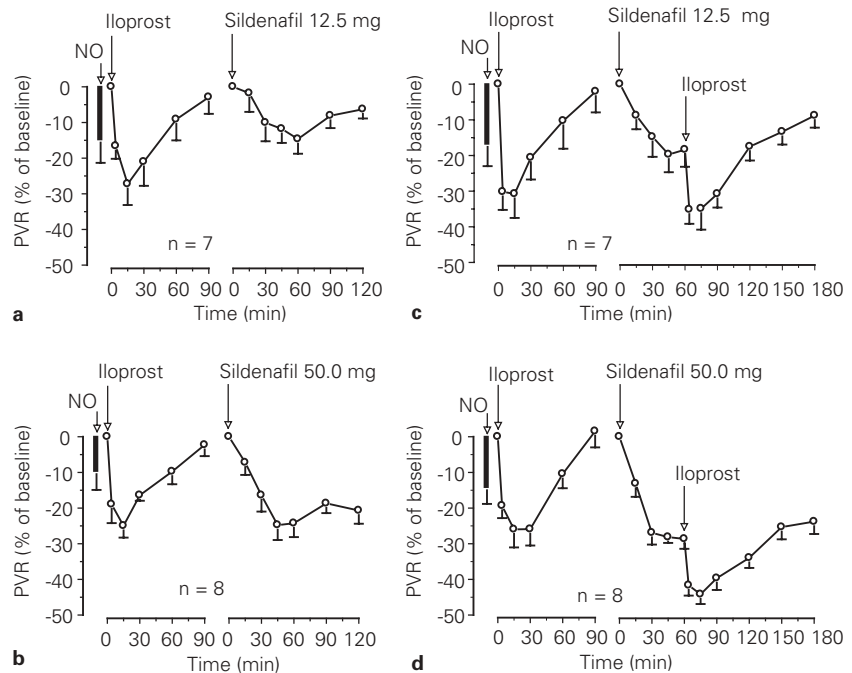
Die gemeinsame Endstrecke in der Wirkungssequenz der endogenen vasodilatativen Mediatoren (z.B. NO, Prostaglandine und atriales natriuretisches Peptid [ANP]) ist die intrazelluläre Freisetzung zyklischer Nucleotide (zyklisches Adenosinmonophosphat [cAMP], zyklisches Guanosinmonophosphat [cGMP]). Diese sog. Second Messenger werden in erster Linie durch eine Aktivierung von Adenylat- und Guanylatcyclase gebildet [9]. Der Abbau zyklischer Nucleotide durch Phosphodiesterasen (PDE) limitiert die Wirkintensität und -dauer der vasodilatativen Agonisten [9, 10]. PDE zeigen z.T. organ- bzw. zellspezifische Verteilungsmuster [10, 11]. So ist die PDE5 sowohl im Corpus cavernosum des Mannes als auch in der Lunge schon unter physiolo-

gischen Bedingungen hoch exprimiert [10]. Darüber hinaus sind PDE gerade bei verschiedenen proliferativen und konstriktiven Gefäßerkrankungen überexprimiert. PDE-Inhibitoren können, abhängig von ihrem Selektivitätsprofil, in den Abbau von cAMP oder cGMP oder beiden Systemen gleichzeitig eingreifen.

Therapeutische Ansätze ergeben sich vor dem Hintergrund dieser pathophysiologischen Überlegungen somit in zweierlei Hinsicht: 1. können PDE-Inhibitoren den basalen Abbau von zyklischen Nucleotiden hemmen und somit per se vasodilatative Effekte erzielen, und 2. können PDE-Inhibitoren die Wirksamkeit von Vasodilatoren wie NO und Prostanoiden verlängern.

Sildenafil. Sildenafil ist ein selektiver PDE5-Inhibitor und zur Therapie der erektilen Dysfunktion zugelassen. In dieser Indikation zeigte das Medikament bisher ein ausgesprochen gutes Sicherheitsprofil, insbesondere ohne Nachweis relevanter systemischer Blutdrucksenkung [12]. Bei Patienten, die aufgrund einer kardiovaskulären Erkrankung mit Nitropräparaten therapiert werden, sollte jedoch zur Vermeidung unerwünschter schwerer Hypotonien von einer kombinierten Anwendung mit Sildenafil abgesehen werden.

Basierend auf experimentellen Vorkenntnissen lag es nahe, PDE-Inhibitoren zur Verlängerung und/oder Verstärkung der Wirkung von Prostanoiden einzusetzen. Zwei klinische Studien haben hierbei eindrucksvoll belegen können, dass Sildenafil per se ein potenter pulmonaler Vasodilatator ist, der trotz systemischer Applikation eine überraschende pulmonale Selektivität aufweist [13, 14]. Des Weiteren konnte eine deutliche synergistische Wirkung von oralem Sildenafil mit inhaliertem Iloprost dokumentiert werden. An 30 Patienten mit schwerer pulmonaler Hypertonie wurde hierbei ein Vergleich der Wirksamkeit mit dem bekanntermaßen pulmonal selektiven Vasodilatator inhaliertes NO durchge-



Abbildungen 1a bis 1d. Wirkung von inhaliertem Stickstoffmonoxid (NO) und Iloprost sowie oralem Sildenafil auf den pulmonalvaskulären Widerstand (PVR; modifiziert nach [14]). Die prozentuale Reduktion des PVR unter NO-Inhalation, Iloprostinhalation und nach oralem Sildenafil ist hier dargestellt. a, b) Untersuchung einzelner Anwendungen der Medikamente. c, d) Zusätzliche Darstellung der kombinierten Gaben von Sildenafil – c) 12,5 mg, d) 50 mg – mit inhaliertem Iloprost (Ilomedin®).

Figures 1a to 1d. Comparison of pulmonary vasodilative potency of oral sildenafil, inhaled nitric oxide (NO) and inhaled iloprost (adapted from [14]). Comparative vasodilator testing was performed in 30 patients with precapillary pulmonary hypertension. The relative reduction (in %) of PVR subsequent to inhaled NO, inhaled iloprost, and oral sildenafil is presented. a, b) Investigation of the effects of each single substance. c, d) Combinations of inhaled iloprost with 12.5 mg (c) and 50 mg (d) oral sildenafil are displayed.

führt [14]. Hierbei zeigte sich, dass 50 mg orales Sildenafil eine signifikant stärkere pulmonale Vasodilatation bewirkte als inhaliertes NO (PVR-Reduktion: ~ 25% [50 mg Sildenafil] vs. ~ 15% [~ 20 ppm NO]; Abbildung 1). Im Hinblick auf mögliche kombinierte Anwendungen von PDE-Inhibitoren und Prostanoiden zeigten beide Substanzen in dieser Studie einen eindrucksvollen Synergismus der Wirksamkeit (> 45% PVR-Reduktion), bei erhaltener pulmonal selektiver Wirkweise und somit sehr guter Verträglichkeit. Auch bei pulmonaler Hypertonie als Begleiterkrankung einer interstitiellen Lungenerkrankung zeigte Sildenafil ein einzigartiges Wirkprofil. Obwohl Patienten mit Lungenfibrose und pulmonaler Hypertonie eine Prädisposition zu Oxygenierungsstörungen unter der Gabe von nichtselektiven Vasodilatoren haben, zeigte Sildenafil bei diesen Patienten (trotz oraler Gabe) nicht nur eine Se-

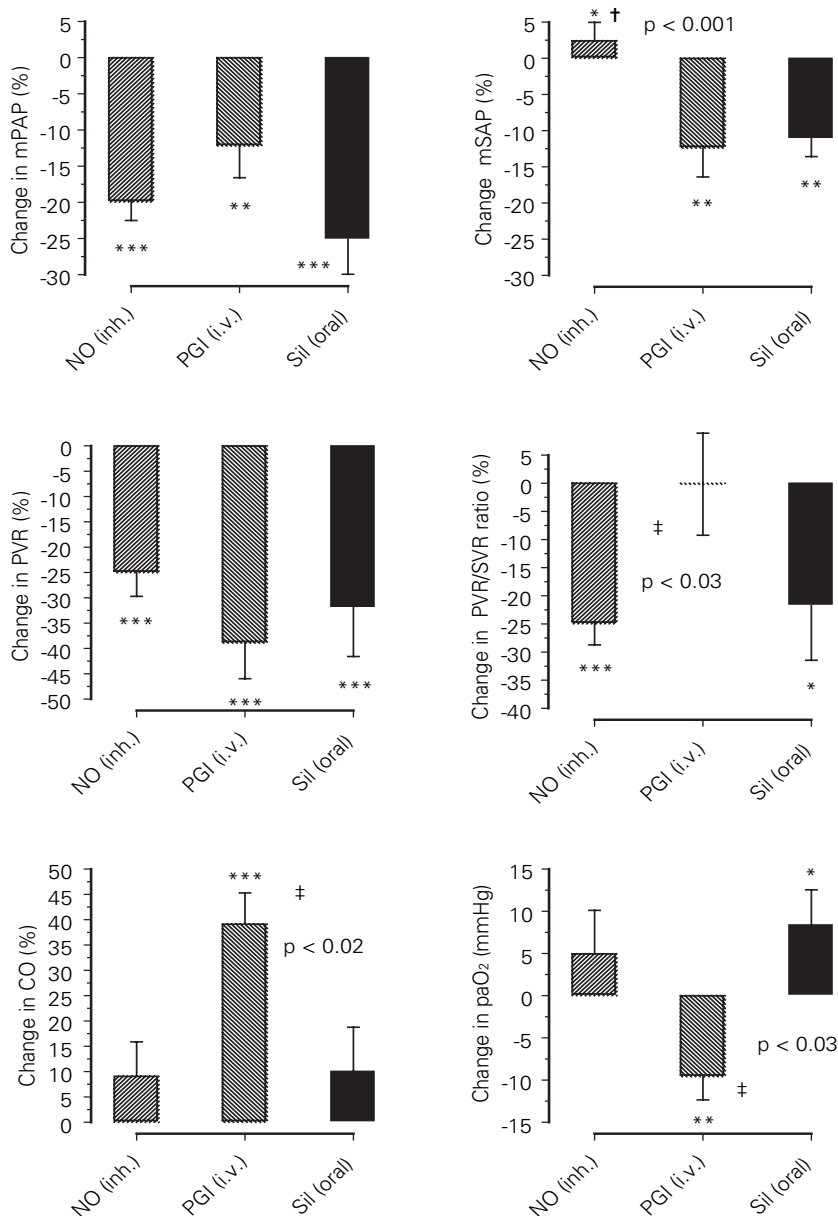


Abbildung 2. Hämodynamische und Gasaustauschveränderungen bei Patienten mit Lungenfibrose und schwerer pulmonaler Hypertonie (modifiziert nach [15]).

Relative Veränderungen der Messparameter nach Inhalation mit Stickstoffmonoxid [NO (inh.)], intravenösem Prostacyclin [PGI (i.v.)] und oralem Sildenafil [Sil (oral)] sind hier dargestellt. CO: Herzzeitvolumen; mPAP: mittlerer pulmonalarterieller Druck; mSAP: mittlerer systemisch-arterieller Druck; paO₂: arterieller Sauerstoffpartialdruck; PVR: pulmonalvaskulärer Widerstand; PVR/SVR: Relation von pulmonal- zu systemisch-vaskulärem Widerstand.

Figure 2. Hemodynamic and gas exchange response to inhaled nitric oxide [NO (inh.)], infused prostacyclin [PGI (i.v.)], and oral sildenafil [Sil (oral)] in patients with lung fibrosis and pulmonary hypertension (adapted from [15]).

Deviations from pre-intervention baseline are displayed for inhaled NO, infused prostacyclin, and oral sildenafil. CO: cardiac output; mPAP: mean pulmonary arterial pressure; mSAP: mean systemic arterial pressure; paO₂: partial pressure of arterial oxygen (changes given in mm Hg); PVR: pulmonary vascular resistance index; PVR/SVR ratio: ratio of pulmonary to systemic vascular resistance.

ektivität im Sinne einer bevorzugten Senkung des PVR, sondern auch im Sinne einer intrapulmonalen Selektivität, welche sich in einer Verbesserung des Gasaustauschs ausdrückte [15] (Abbildung 2).

In einer kürzlich publizierten Untersuchung konnte durch Sildenafil erstmalig eine Leistungssteigerung bei hypoxieinduzierter pulmonaler Hypertonie dokumentiert werden, welche nicht nur mit einer Drucksenkung im kleinen Kreislauf, sondern auch mit einer verbesserten Oxygenierung einherging [16].

Mittlerweile ist die zulassungsrelevante Phase-III-Studie zur Behandlung der PAH mit Sildenafil zum Abschluss gekommen. Die Ergebnisse wurden 2004 auf der Konferenz der ACCP (American College of Chest Physicians) in Seattle, WA, USA, vorgestellt. Hierbei zeigte sich Sildenafil in allen drei getesteten Dosen von 20 mg, 40 mg und 80 mg (jeweils dreimal täglich verabreicht) hochsignifikant wirksamer in Bezug auf das Erreichen des primären Endpunkts (Verbesserung der 6-min-Gehstrecke; bis zu 50 m in der 80-mg-Gruppe) als Placebo. Auch sekundäre Parameter, wie die Verbesserung der pulmonalen Hämodynamik sowie Parameter der Lebensqualität, waren signifikant verbessert. Zwischenzeitlich ist die Zulassung des Medikaments bei den US-amerikanischen und europäischen Behörden beantragt.

Kombinationstherapien

In der klinischen Realität von Patienten mit schwerer chronischer pulmonaler Hypertonie ergibt sich leider häufig die Situation, dass es trotz chronischer Therapie mit Prostanoiden oder Endothelinantagonisten zu einer progredienten Verschlechterung des klinischen Zustands der

Patienten kommt. Bisher wurden Patienten in einer solchen Konstellation einer atrialen Septostomie als überbrückende Maßnahme oder direkt einer Lungentransplantation zugeführt (mit allen Einschränkungen, bedingt durch lange Wartezeiten auf Spenderorgane und bisher unbefriedigende Langzeitergebnisse nach Transplantation). Wie erwähnt, zeigt Sildenafil auch in der Kombination mit z.B. inhaliertem Iloprost ein ausgesprochen gutes Wirkprofil bei dosisabhängig erhaltener pulmonaler Selektivität [14]. Eigene Erfahrungen bezüglich der kombinierten Langzeitanwendung von Sildenafil mit inhaliertem Iloprost im Rahmen klinischer Heilversuche erbrachten hierbei sehr ermutigende Ergebnisse im Sinne einer Rekompensation von Patienten, die trotz laufender Inhalationstherapie mit Iloprost zu dekompensieren drohten [17]. Eine weitere Untersuchung zur kombinierten Anwendung von Sildenafil und Bosentan zeigte ebenfalls einen Synergismus beider Therapien in Bezug auf eine Verbesserung der körperlichen Belastbarkeit [18]. Größere, plazebokontrollierte Studien sind notwendig, um abschließend die Fragen zu klären, 1. ob die Initiierung einer medikamentösen Therapie der pulmonalen Hypertonie mit mehreren Substanzen (z.B. PDE-Inhibitoren + Prostanoiden oder PDE-Inhibitoren + ERA oder Prostanoiden + ERA) einer einzelnen Therapie überlegen ist, 2. ob sich Patienten, die sich unter einer Monotherapie verschlechtern, durch Hinzunahme einer weiteren aktiven Substanz verbessern lassen, und 3. welche Medikamentenkombination im Hinblick auf Effektivität und Verbesserung der Prognose am wirksamsten ist. Die Optimierung der funktionellen Belastbarkeit bei Patienten mit chronischen pulmonalen Hypertonien sollte jeweils im Zentrum der therapeutischen Anstrengungen stehen, da diese von prognostischer Relevanz ist [19, 20]. Möglicherweise werden in Zukunft Kombinationen aus drei oder gar mehr Medikamenten zum Standardregime in der Behandlung der pulmonalen Hypertonie gehören, um dieses Ziel zu realisieren.

Behandlung von Frühformen der pulmonalen Hypertonie

Derzeit gibt es keine generelle Empfehlung zur Therapie von Frühformen der pulmonalen Hypertonie mit Vasodilanzien. Die Rationale für den frühzeitigen Einsatz solcher Substanzen ergibt sich aus der Vorstellung, sekundäre chronische (irreversible) Umbauprozesse der Lungengefäße zu verhindern, die sich im Gefolge dauerhafter Vasokonstriktion (prinzipiell noch

reversibel) ausbilden können. Die bisherige Zurückhaltung bezüglich einer frühzeitigen medikamentösen Therapie ist sicherlich zum einen durch die hohen Kosten der etablierten Medikamente in Verbindung mit dem hohen apparativen Aufwand und zum anderen mit den teils erheblichen therapiassoziierten Nebenwirkungen zu erklären. Außerdem zeigte sich in Bezug auf einen therapeutischen Nutzen für infundierte Prostanoiden, dass nur Patienten mit einem weit fortgeschrittenen Stadium der Erkrankung einen signifikanten Überlebensvorteil aufwiesen, während diejenigen mit milderen Formen sogar tendenziell nachteilige Langzeitergebnisse durch die Therapie aufwiesen [21].

Aufgrund des sehr guten Sicherheitsprofils, der hohen Wirksamkeit und der verhältnismäßig niedrigen Therapiekosten könnte zukünftig dem oralen Sildenafil in der frühzeitigen Therapie latenter oder milder pulmonaler Hypertonien eine wichtige Rolle zukommen, zumal auch in der zulassungsrelevanten Phase-III-Studie mit dieser Substanz ein hoher Anteil von Patienten mit funktioneller NYHA-Klasse II erfolgreich behandelt werden konnte. Ebenso könnte dies für inhalierte Prostanoiden bei weiterer Vereinfachung der Inhalationstechnologie zutreffen. Studien zu diesen Fragen stehen jedoch noch aus.

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Korrespondenzanschrift

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EXHIBIT C

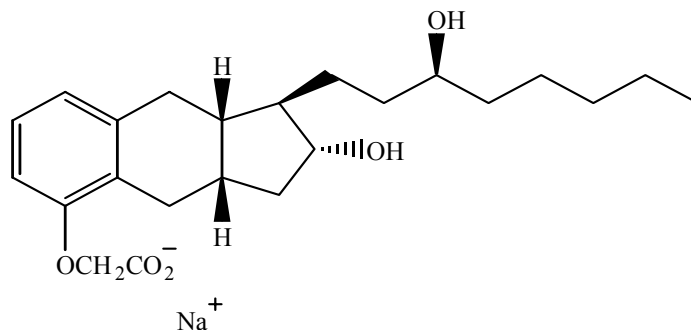
PRODUCT INFORMATION**REMODULIN[®] (Treprostinil sodium) Injection****DESCRIPTION**

Remodulin[®] (treprostinil sodium) Injection is a sterile sodium salt formulated for subcutaneous or intravenous administration. Remodulin is supplied in 20 mL multi-use vials in four strengths, containing 1 mg/mL, 2.5 mg/mL, 5 mg/mL or 10 mg/mL of treprostinil. Each mL also contains 5.3 mg sodium chloride (except for the 10 mg/mL strength which contains 4.0 mg sodium chloride), 3.0 mg metacresol, 6.3 mg sodium citrate, and water for injection. Sodium hydroxide and hydrochloric acid may be added to adjust pH between 6.0 and 7.2.

Treprostinil is chemically stable at room temperature and neutral pH.

Treprostinil sodium is (1R,2R,3aS,9aS)-[[2,3,3a,4,9,9a-Hexahydro-2-hydroxy-1-[(3S)-3-hydroxyoctyl]-1H-benz[f]inden-5-yl]oxy]acetic acid monosodium salt. Treprostinil sodium has a molecular weight of 412.49 and a molecular formula of C₂₃H₃₃NaO₅.

The structural formula of treprostinil sodium is:

**CLINICAL PHARMACOLOGY**

General: The major pharmacologic actions of treprostinil are direct vasodilation of pulmonary and systemic arterial vascular beds and inhibition of platelet aggregation. In animals, the vasodilatory effects reduce right and left ventricular afterload and increase cardiac output and stroke volume. Other studies have shown that treprostinil causes a dose-related negative inotropic and lusitropic effect. No major effects on cardiac conduction have been observed.

Pharmacokinetics

The pharmacokinetics of continuous subcutaneous Remodulin are linear over the dose range of 1.25 to 22.5 ng/kg/min (corresponding to plasma concentrations of about 0.03 to 8 mcg/L) and can be described by a two-compartment model. Dose proportionality at infusion rates greater than 22.5 ng/kg/min has not been studied.

Subcutaneous and intravenous administration of Remodulin demonstrated bioequivalence at steady state at a dose of 10 ng/kg/min.

Absorption: Remodulin is relatively rapidly and completely absorbed after subcutaneous infusion, with an absolute bioavailability approximating 100%. Steady-state concentrations occurred in approximately 10 hours. Concentrations in patients treated with an average dose of 9.3 ng/kg/min were approximately 2 mcg/L.

Distribution: The volume of distribution of the drug in the central compartment is approximately 14L/70 kg ideal body weight. Remodulin at *in vitro* concentrations ranging from 330-10,000 mcg/L was 91% bound to human plasma protein.

Metabolism: Remodulin is substantially metabolized by the liver, but the precise enzymes responsible are unknown. Five metabolites have been described (HU1 through HU5). The biological activity and metabolic fate of these metabolites are unknown. The chemical structure of HU1 is unknown. HU5 is the glucuronide conjugate of treprostinil. The other

metabolites are formed by oxidation of the 3-hydroxyoctyl side chain (HU2) and subsequent additional oxidation (HU3) or dehydration (HU4). Based on the results of *in vitro* human hepatic cytochrome P450 studies, Remodulin does not inhibit CYP-1A2, 2C9, 2C19, 2D6, 2E1, or 3A. Whether Remodulin induces these enzymes has not been studied.

Excretion: The elimination of Remodulin is biphasic, with a terminal half-life of approximately 4 hours. Approximately 79% of an administered dose is excreted in the urine as unchanged drug (4%) and as the identified metabolites (64%). Approximately 13% of a dose is excreted in the feces. Systemic clearance is approximately 30 liters/hr for a 70 kg ideal body weight person.

Special Populations

Hepatic Insufficiency: In patients with portopulmonary hypertension and mild (n=4) or moderate (n=5) hepatic insufficiency, Remodulin at a subcutaneous dose of 10 ng/kg/min for 150 minutes had a C_{max} that was increased 2-fold and 4-fold, respectively, and an $AUC_{0-\infty}$ that was increased 3-fold and 5-fold, respectively, compared to healthy subjects. Clearance in patients with hepatic insufficiency was reduced by up to 80% compared to healthy adults.

In patients with mild or moderate hepatic insufficiency, the initial dose of Remodulin should be decreased to 0.625 ng/kg/min ideal body weight and should be increased cautiously. Remodulin has not been studied in patients with severe hepatic insufficiency.

Renal Insufficiency: No studies have been performed in patients with renal insufficiency, so no specific advice about dosing in such patients can be given. Although only 4% of the administered dose is excreted unchanged in the urine, the five identified metabolites are all excreted in the urine.

Effect of Other Drugs on Remodulin: *In vitro* studies: Remodulin did not significantly affect the plasma protein binding of normally observed concentrations of digoxin or warfarin.

In vivo studies: Acetaminophen - Analgesic doses of acetaminophen, 1000 mg every 6 hours for seven doses, did not affect the pharmacokinetics of Remodulin, at a subcutaneous infusion rate of 15 ng/kg/min.

Clinical Trials in Pulmonary Arterial Hypertension (PAH)

Two 12-week, multicenter, randomized, double-blind studies compared continuous subcutaneous infusion of Remodulin to placebo in a total of 470 patients with NYHA Class II-IV pulmonary arterial hypertension (PAH). PAH was primary in 58% of patients, associated with collagen vascular disease in 19%, and the result of congenital left to right shunts in 23%. The mean age was 45 (range 9 to 75 years). About 81% were female and 84% were Caucasian. Pulmonary hypertension had been diagnosed for a mean of 3.8 years. The primary endpoint of the studies was change in 6-minute walking distance, a standard measure of exercise capacity. There were many assessments of symptoms related to heart failure, but local discomfort and pain associated with Remodulin may have substantially unblinded those assessments. The 6-minute walking distance and an associated subjective measurement of shortness of breath during the walk (Borg dyspnea score) were administered by a person not participating in other aspects of the study. Remodulin was administered as a subcutaneous infusion, described in DOSAGE AND ADMINISTRATION, and the dose averaged 9.3 ng/kg/min at Week 12. Few subjects received doses > 40 ng/kg/min. Background therapy, determined by the investigators, could include anticoagulants, oral vasodilators, diuretics, digoxin, and oxygen but not an endothelin receptor antagonist or epoprostenol. The two studies were identical in design and conducted simultaneously, and the results were analyzed both pooled and individually.

Hemodynamic Effects

As shown in Table 1, chronic therapy with Remodulin resulted in small hemodynamic changes consistent with pulmonary and systemic vasodilation.

Table 1: Hemodynamics During Chronic Administration of Remodulin in Patients with PAH

Hemodynamic Parameter	Baseline		Mean change from baseline at Week 12	
	Remodulin (N=204-231)	Placebo (N=215-235)	Remodulin (N=163-199)	Placebo (N=182-215)
CI (L/min/m ²)	2.4 ± 0.88	2.2 ± 0.74	+0.12 ± 0.58*	-0.06 ± 0.55
PAPm (mmHg)	62 ± 17.6	60 ± 14.8	-2.3 ± 7.3*	+0.7 ± 8.5
RAPm (mmHg)	10 ± 5.7	10 ± 5.9	-0.5 ± 5.0*	+1.4 ± 4.8
PVRI (mmHg/L/min/m ²)	26 ± 13	25 ± 13	-3.5 ± 8.2*	+1.2 ± 7.9
SVRI (mmHg/L/min/m ²)	38 ± 15	39 ± 15	-3.5 ± 12*	-0.80 ± 12
SvO ₂ (%)	62 ± 100	60 ± 11	+2.0 ± 10*	-1.4 ± 8.8
SAPm (mmHg)	90 ± 14	91 ± 14	-1.7 ± 12	-1.0 ± 13
HR (bpm)	82 ± 13	82 ± 15	-0.5 ± 11	-0.8 ± 11

*Denotes statistically significant difference between Remodulin and placebo, p<0.05.

CI = cardiac index; PAPm = mean pulmonary arterial pressure; PVRI = pulmonary vascular resistance indexed; RAPm = mean right atrial pressure; SAPm = mean systemic arterial pressure; SVRI = systemic vascular resistance indexed;

SvO₂ = mixed venous oxygen saturation; HR = heart rate.

Clinical Effects

The effect of Remodulin on 6-minute walk, the primary end point of the studies, was small and did not achieve conventional levels of statistical significance. For the combined populations, the median change from baseline on Remodulin was 10 meters and the median change from baseline on placebo was 0 meters. Although it was not the primary endpoint of the study, the Borg dyspnea score was significantly improved by Remodulin during the 6-minute walk, and Remodulin also had a significant effect, compared with placebo, on an assessment that combined walking distance with the Borg dyspnea score. Remodulin also consistently improved indices of dyspnea, fatigue and signs and symptoms of pulmonary hypertension, but these indices were difficult to interpret in the context of incomplete blinding to treatment assignment resulting from infusion site symptoms.

INDICATIONS AND USAGE

Remodulin[®] is indicated as a continuous subcutaneous infusion or intravenous infusion (for those not able to tolerate a subcutaneous infusion) for the treatment of pulmonary arterial hypertension in patients with NYHA Class II-IV symptoms (see **CLINICAL PHARMACOLOGY: Clinical Effects**) to diminish symptoms associated with exercise.

CONTRAINDICATIONS

Remodulin is contraindicated in patients with known hypersensitivity to the drug or to structurally related compounds.

WARNINGS

Remodulin is indicated for subcutaneous or intravenous use only.

PRECAUTIONS

General

Remodulin should be used only by clinicians experienced in the diagnosis and treatment of PAH.

Remodulin is a potent pulmonary and systemic vasodilator. Initiation of Remodulin must be performed in a setting with adequate personnel and equipment for physiological monitoring and emergency care. Therapy with Remodulin may be used for prolonged periods, and the patient's ability to administer Remodulin and care for an infusion system should be carefully considered.

Dose should be increased for lack of improvement in, or worsening of, symptoms and it should be decreased for excessive pharmacologic effects or for unacceptable infusion site symptoms (see **DOSAGE AND ADMINISTRATION**).

Abrupt withdrawal or sudden large reductions in dosage of Remodulin may result in worsening of PAH symptoms and should be avoided.

Information for Patients

Patients receiving Remodulin should be given the following information: Remodulin is infused continuously through a subcutaneous or surgically placed indwelling central venous catheter, via an infusion pump. Therapy with Remodulin will be needed for prolonged periods, possibly years, and the patient's ability to accept and care for a catheter and to use an infusion pump should be carefully considered. In order to reduce the risk of infection, aseptic technique must be used in the preparation and administration of Remodulin. Additionally, patients should be aware that subsequent disease management may require the initiation of an alternative intravenous prostacyclin therapy, Flolan[®] (epoprostenol sodium).

Drug Interactions

Reduction in blood pressure caused by Remodulin may be exacerbated by drugs that by themselves alter blood pressure, such as diuretics, antihypertensive agents, or vasodilators. Since Remodulin inhibits platelet aggregation, there is also a potential for increased risk of bleeding, particularly among patients maintained on anticoagulants. During clinical trials, Remodulin was used concurrently with anticoagulants, diuretics, cardiac glycosides, calcium channel blockers, analgesics, antipyretics, nonsteroidal anti-inflammatories, opioids, corticosteroids, and other medications.

Remodulin has not been studied in conjunction with Flolan or Tracleer[®] (bosentan).

Effect of Other Drugs on Remodulin

In vivo studies: Acetaminophen - Analgesic doses of acetaminophen, 1000 mg every 6 hours for seven doses, did not affect the pharmacokinetics of Remodulin, at a subcutaneous infusion rate of 15 ng/kg/min.

Effect of Remodulin on Other Drugs

In vitro studies: Remodulin did not significantly affect the plasma protein binding of normally observed concentrations of digoxin or warfarin.

In vivo studies: Warfarin - Remodulin does not affect the pharmacokinetics or pharmacodynamics of warfarin. The pharmacokinetics of R- and S- warfarin and the INR in healthy subjects given a single 25 mg dose of warfarin were unaffected by continuous subcutaneous Remodulin at an infusion rate of 10 ng/kg/min.

Hepatic and Renal Impairment

Caution should be used in patients with hepatic or renal impairment (see **Special Populations**).

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies have not been performed to evaluate the carcinogenic potential of treprostinil. *In vitro* and *in vivo* genetic toxicology studies did not demonstrate any mutagenic or clastogenic effects of treprostinil. Treprostinil sodium did not affect fertility or mating performance of male or female rats given continuous subcutaneous infusions at rates of up to 450 ng treprostinil/kg/min [about 59 times the recommended starting human rate of infusion (1.25 ng/kg/min) and about 8 times the average rate (9.3 ng/kg/min) achieved in clinical trials, on a ng/m² basis]. In this study, males were dosed from 10 weeks prior to mating and through the 2-week mating period. Females were dosed from 2 weeks prior to mating until gestational day 6.

Pregnancy

Pregnancy Category B - In pregnant rats, continuous subcutaneous infusions of treprostinil sodium during organogenesis and late gestational development, at rates as high as 900 ng treprostinil/kg/min (about 117 times the starting human rate of infusion, on a ng/m² basis and about 16 times the average rate achieved in clinical trials), resulted in no evidence of harm to the fetus. In pregnant rabbits, effects of continuous subcutaneous infusions of treprostinil during organogenesis were limited to an increased incidence of fetal skeletal variations (bilateral full rib or right rudimentary rib on lumbar 1) associated with maternal toxicity (reduction in body weight and food consumption) at an infusion rate of 150 ng treprostinil/kg/min (about 41 times the starting human rate of infusion, on a ng/m² basis, and 5 times the average rate used in clinical trials). In rats, continuous subcutaneous infusion of treprostinil from implantation to the end of lactation, at rates of up to 450 ng treprostinil/kg/min, did not affect the growth and development of offspring. Because animal reproduction studies are not always predictive of human response, Remodulin should be used during pregnancy only if clearly needed.

Labor and delivery

No treprostinil sodium treatment-related effects on labor and delivery were seen in animal studies. The effect of treprostinil sodium on labor and delivery in humans is unknown.

Nursing mothers

It is not known whether treprostinil is excreted in human milk or absorbed systemically after ingestion. Because many drugs are excreted in human milk, caution should be exercised when Remodulin is administered to nursing women.

Pediatric use

Safety and effectiveness in pediatric patients have not been established. Clinical studies of Remodulin did not include sufficient numbers of patients aged ≤16 years to determine whether they respond differently from older patients. In general, dose selection should be cautious.

Geriatric use

Clinical studies of Remodulin did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS

Patients receiving Remodulin as a subcutaneous infusion reported a wide range of adverse events, many potentially related to the underlying disease (dyspnea, fatigue, chest pain, right ventricular heart failure, and pallor). During clinical trials with subcutaneous infusion of Remodulin, infusion site pain and reaction were the most common adverse events among those treated with Remodulin. Infusion site reaction was defined as any local adverse event other than pain or bleeding/bruising at the infusion site and included symptoms such as erythema, induration or rash. Infusion site reactions were sometimes severe and could lead to discontinuation of treatment.

Table 2. Percentages of subjects reporting subcutaneous infusion site adverse events

	Reaction		Pain	
	Placebo	Remodulin	Placebo	Remodulin
Severe	1	38	2	39
Requiring narcotics*	NA**	NA**	1	32
Leading to discontinuation	0	3	0	7

* based on prescriptions for narcotics, not actual use

**medications used to treat infusion site pain were not distinguished from those used to treat site reactions

Other adverse events included diarrhea, jaw pain, edema, vasodilatation and nausea, and these are generally considered to be related to the pharmacologic effects of Remodulin, whether administered subcutaneously or intravenously.

Adverse Events During Chronic Dosing

Table 3 lists adverse events that occurred at a rate of at least 3% and were more frequent in patients treated with subcutaneous Remodulin than with placebo in controlled trials in PAH.

Table 3: Adverse Events in Controlled Studies of Patients with PAH, Occurring with at Least 3% Incidence and More Common on Subcutaneous Remodulin than on Placebo.

Adverse Event	Remodulin (N=236) Percent of Patients	Placebo (N=233) Percent of Patients
Infusion Site Pain	85	27
Infusion Site Reaction	83	27
Headache	27	23
Diarrhea	25	16
Nausea	22	18
Rash	14	11
Jaw Pain	13	5
Vasodilatation	11	5
Dizziness	9	8
Edema	9	3
Pruritus	8	6
Hypotension	4	2

Reported adverse events (at least 3%) are included except those too general to be informative, and those not plausibly attributable to the use of the drug, because they were associated with the condition being treated or are very common in the treated population.

Adverse Events Attributable to the Drug Delivery System

In controlled studies of Remodulin administered subcutaneously, there were no reports of infection related to the drug delivery system. There were 187 infusion system complications reported in 28% of patients (23% Remodulin, 33% placebo); 173 (93%) were pump related and 14 (7%) related to the infusion set. Eight of these patients (4 Remodulin, 4 Placebo) reported non-serious adverse events resulting from infusion system complications. Adverse events resulting from problems with the delivery systems were typically related to either symptoms of excess Remodulin (e.g., nausea) or return of PAH symptoms (e.g., dyspnea). These events were generally resolved by correcting the delivery system pump or infusion set problem such as replacing the syringe or battery, reprogramming the pump, straightening a crimped infusion line. Adverse events resulting from problems with the delivery system did not lead to clinical instability or rapid deterioration.

There are no controlled clinical studies with Remodulin administered intravenously. Among the subjects (n=38) treated for 12-weeks in an open-label study, 2 patients had either line infections or sepsis. Other events potentially related to the mode of infusion include arm swelling, paresthesias, hematoma and pain.

OVERDOSAGE

Signs and symptoms of overdose with Remodulin during clinical trials are extensions of its dose-limiting pharmacologic effects and include flushing, headache, hypotension, nausea, vomiting, and diarrhea. Most events were self-limiting and resolved with reduction or withholding of Remodulin.

In controlled clinical trials, seven patients received some level of overdose and in open-label follow-on treatment seven additional patients received an overdose; these occurrences resulted from accidental bolus administration of Remodulin, errors in pump programmed rate of administration, and prescription of an incorrect dose. In only two cases did excess delivery of Remodulin produce an event of substantial hemodynamic concern (hypotension, near-syncope).

DOSAGE AND ADMINISTRATION

Remodulin® is supplied in 20 mL vials in concentrations of 1 mg/mL, 2.5 mg/mL, 5 mg/mL and 10 mg/mL. Remodulin can be administered as supplied or diluted for intravenous infusion with Sterile Water for Injection or 0.9% Sodium Chloride Injection prior to administration.

Initial Dose

Remodulin is administered by continuous infusion. Remodulin is preferably infused subcutaneously, but can be administered by a central intravenous line if the subcutaneous route is not tolerated, because of severe site pain or reaction. The infusion rate is initiated at 1.25 ng/kg/min. If this initial dose cannot be tolerated because of systemic effects, the infusion rate should be reduced to 0.625 ng/kg/min.

Dosage Adjustments

The goal of chronic dosage adjustments is to establish a dose at which PAH symptoms are improved, while minimizing excessive pharmacologic effects of Remodulin (headache, nausea, emesis, restlessness, anxiety and infusion site pain or reaction).

The infusion rate should be increased in increments of no more than 1.25 ng/kg/min per week for the first four weeks and then no more than 2.5 ng/kg/min per week for the remaining duration of infusion, depending on clinical response. There is little experience with doses >40 ng/kg/min. Abrupt cessation of infusion should be avoided (see **PRECAUTIONS**).

Administration

Subcutaneous Infusion

Remodulin is administered subcutaneously by continuous infusion, via a self-inserted subcutaneous catheter, using an infusion pump designed for subcutaneous drug delivery. To avoid potential interruptions in drug delivery, the patient must have immediate access to a backup infusion pump and subcutaneous infusion sets. The ambulatory infusion pump used to administer Remodulin should: (1) be small and lightweight, (2) be adjustable to approximately 0.002 mL/hr, (3) have occlusion/no delivery, low battery, programming error and motor malfunction alarms, (4) have delivery accuracy of ±6% or better and (5) be positive pressure driven. The reservoir should be made of polyvinyl chloride, polypropylene or glass.

For subcutaneous infusion, Remodulin is **delivered without further dilution** at a calculated Subcutaneous Infusion Rate (mL/hr) based on a patient's Dose (ng/kg/min), Weight (kg), and the Vial Strength (mg/mL) of Remodulin being used. During use, a single reservoir (syringe) of undiluted Remodulin can be administered up to 72 hours at 37°C. The Subcutaneous Infusion rate is calculated using the following formula:

$$\text{Subcutaneous Infusion Rate (mL/hr)} = \frac{\text{Dose (ng/kg/min)} \times \text{Weight (kg)} \times 0.00006^*}{\text{Remodulin Vial Strength (mg/mL)}}$$

*Conversion factor of 0.00006 = 60 min/hour x 0.000001 mg/ng

Example calculations for *Subcutaneous Infusion* are as follows:

Example 1:

For a 60 kg person at the recommended initial dose of 1.25 ng/kg/min using the 1 mg/mL Remodulin Vial Strength, the infusion rate would be calculated as follows:

$$\text{Subcutaneous Infusion Rate (mL/hr)} = \frac{1.25 \text{ ng/kg/min} \times 60 \text{ kg} \times 0.00006}{1 \text{ mg/mL}} = 0.005 \text{ mL/hr}$$

Example 2:

For a 65 kg person at a dose of 40 ng/kg/min using the 5 mg/mL Remodulin Vial Strength, the infusion rate would be calculated as follows:

$$\text{Subcutaneous Infusion Rate (mL/hr)} = \frac{40 \text{ ng/kg/min} \times 65 \text{ kg} \times 0.00006}{5 \text{ mg/mL}} = 0.031 \text{ mL/hr}$$

Intravenous Infusion

Remodulin must be diluted with either Sterile Water for Injection or 0.9% Sodium Chloride Injection and is administered intravenously by continuous infusion, via a surgically placed indwelling central venous catheter, using an infusion pump designed for intravenous drug delivery. To avoid potential interruptions in drug delivery, the patient must have immediate access to a backup infusion pump and infusion sets. The ambulatory infusion pump used to administer Remodulin should: (1) be small and lightweight, (2) have occlusion/no delivery, low battery, programming error and motor malfunction alarms, (3) have delivery accuracy of ±6% or better of the hourly dose, and (4) be positive pressure driven. The reservoir should be made of polyvinyl chloride, polypropylene or glass.

Diluted Remodulin has been shown to be stable at ambient temperature for up to 48 hours at concentrations as low as 0.004 mg/mL (4,000 ng/mL).

When using an appropriate infusion pump and reservoir, a predetermined intravenous infusion rate should first be selected to allow for a desired infusion period length of up to 48 hours between system changeovers. Typical intravenous infusion system reservoirs have volumes of 50 or 100 mL. With this selected Intravenous Infusion Rate (mL/hr) and the patient's Dose (ng/kg/min) and Weight (kg), the Diluted Intravenous Remodulin Concentration (mg/mL) can be calculated using the following formula:

$$\text{Step 1 Diluted Intravenous Remodulin Concentration (mg/mL)} = \frac{\text{Dose (ng/kg/min)} \times \text{Weight (kg)} \times 0.00006}{\text{Intravenous Infusion Rate (mL/hr)}}$$

The Amount of Remodulin Injection needed to make the required Diluted Intravenous Remodulin Concentration for the given reservoir size can then be calculated using the following formula:

Step 2 Amount of Remodulin Injection (mL)	=	Diluted Intravenous Remodulin Concentration (mg/mL)	x	Total Volume of Diluted Remodulin Solution in Reservoir (mL)
		Remodulin Vial Strength (mg/mL)		

The calculated amount of Remodulin Injection is then added to the reservoir along with the sufficient volume of diluent (Sterile Water for Injection or 0.9% Sodium Chloride Injection) to achieve the desired total volume in the reservoir.

Example calculations for *Intravenous Infusion* are as follows:

Example 3:

For a 60 kg person at a dose of 5 ng/kg/min, with a predetermined intravenous infusion rate of 1 mL/hr and a reservoir of 50 mL, the Diluted Intravenous Remodulin Solution Concentration would be calculated as follows:

Step 1 Diluted Intravenous Remodulin Concentration (mg/mL)	=	$\frac{5 \text{ ng/kg/min} \quad \times \quad 60 \text{ kg} \quad \times \quad 0.00006}{1 \text{ mL/hr}} = 0.018 \text{ mg/mL}$	(18,000 ng/mL)
--	---	---	----------------

The Amount of Remodulin Injection (using 1 mg/mL Vial Strength) needed for a total Diluted Remodulin Concentration of 0.018 mg/mL and a total volume of 50 mL would be calculated as follows:

Step 2 Amount of Remodulin Injection (mL)	=	$\frac{0.018 \text{ mg/mL}}{1 \text{ mg/mL}} \times 50 \text{ mL} = 0.9 \text{ mL}$
---	---	---

The Diluted Intravenous Remodulin Concentration for the person in Example 3 would thus be prepared by adding 0.9 mL of 1 mg/mL Remodulin Injection to a suitable reservoir along with a sufficient volume of diluent to achieve a total volume of 50 mL in the reservoir. The pump flow rate for this example would be set at 1 mL/hr.

Example 4:

For a 75 kg person at a dose of 30 ng/kg/min, with a predetermined intravenous infusion rate of 2 mL/hr, and a reservoir of 100 mL, the Diluted Intravenous Remodulin Solution Concentration would be calculated as follows:

Step 1 Diluted Intravenous Remodulin Concentration (mg/mL)	=	$\frac{30 \text{ ng/kg/min} \quad \times \quad 75 \text{ kg} \quad \times \quad \frac{0.0006}{6}}{2 \text{ mL/hr}} = 0.0675 \text{ mg/mL}$	(67,500 ng/mL)
--	---	--	----------------

The Amount of Remodulin Injection (using 2.5 mg/mL Vial Strength) needed for a total Diluted Remodulin Concentration of 0.0675 mg/mL and a total volume of 100 mL would be calculated as follows:

Step 2 Amount of Remodulin Injection (mL)	=	0.0675 mg/mL	x 100 mL = 2.7 mL
		2.5 mg/mL	

The Diluted Intravenous Remodulin Concentration for the person in Example 4 would thus be prepared by adding 2.7 mL of 2.5 mg/mL Remodulin Injection to a suitable reservoir along with a sufficient volume of diluent to achieve a total volume of 100 mL in the reservoir. The pump flow rate for this example would be set at 2 mL/hr.

HOW SUPPLIED

Remodulin® is supplied in 20 mL multi-use vials at concentrations of 1mg/mL, 2.5 mg/mL, 5 mg/mL, and 10 mg/mL treprostinil, as sterile solutions in water for injection, individually packaged in a carton. Each mL contains treprostinil sodium equivalent to 1mg/mL, 2.5 mg/mL, 5 mg/mL, or 10 mg/mL treprostinil. Unopened vials of Remodulin are stable until the date indicated when stored at 15 to 25°C (59 to 77°F). Store at 25°C (77°F), with excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

During use, a single reservoir (syringe) of undiluted Remodulin can be administered up to 72 hours at 37°C. Diluted Remodulin Solution can be administered up to 48 hours at 37°C when diluted to concentrations as low as 0.004 mg/mL in Sterile Water for Injection or 0.9% Sodium Chloride Injection. A single vial of Remodulin should be used for no more than 30 days after the initial introduction into the vial.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. If either particulate matter or discoloration is noted, Remodulin should not be administered.

20-mL vial containing treprostinil sodium equivalent to 1 mg treprostinil per mL, carton of 1 (NDC 66302-101-01).

20-mL vial containing treprostinil sodium equivalent to 2.5 mg treprostinil per mL, carton of 1 (NDC 66302-102-01).

20-mL vial containing treprostinil sodium equivalent to 5 mg treprostinil per mL, carton of 1 (NDC 66302-105-01).

20-mL vial containing treprostinil sodium equivalent to 10mg treprostinil per mL, carton of 1 (NDC 66302-110-01).

US Patent No. 5,153,222 (Use Patent)

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Research Triangle Park, NC 27709

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REMODULIN manufactured by:

Baxter Pharmaceutical Solutions LLC
Bloomington, IN 47403

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For United Therapeutics Corp.
Research Triangle Park, NC 27709

Rx only

November 2004

EXHIBIT D

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Basic Science

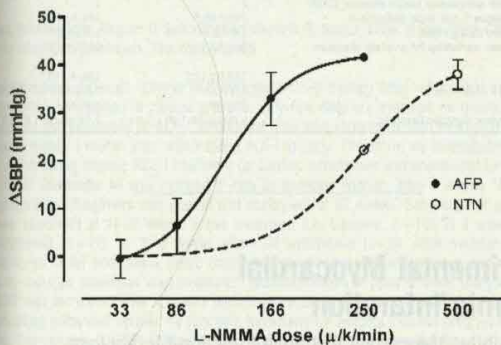
of membranous RhoA and phosphorylated ERM in brainstem were greater both in angiotensin II-treated rats and SHR than in WKY. Valsartan reduced the expression levels of membranous RhoA in angiotensin II-treated rats and SHR. In addition, Y-27632 or valsartan reduced the expression levels of phosphorylated ERM in both groups. Subcutaneous infusion of phenylephrine increased SBP to the same level of angiotensin II infusion in WKY. However, it did not alter the expression levels of membranous RhoA and phosphorylated ERM. Conclusions: These results suggest that 1) the pressor response induced by central infusion of angiotensin II is substantially mediated by activation of Rho/Rho-kinase pathway in brainstem via AT1 receptors, 2) this pathway may also be involved in hypertensive mechanism in SHR.

1412

Endothelial Nitric Oxide and Hypertension in Autonomic Failure

Alfredo Gamboa, Cyndya Shibus, Andre Diedrich, Bonnie K Black, Ginnie Farley, Satish R Raj, David Robertson, Italo Biaggioni; Vanderbilt Univ, Nashville, TN

More than half of patients with autonomic failure (AF) have severe supine hypertension despite low or unresponsive norepinephrine levels and often undetectable plasma renin activity. Supine hypertension is related to increased vascular resistance but the mechanism is not known. To test the hypothesis that nitric oxide deficiency contributes to supine hypertension we blocked endogenous nitric oxide synthase with L-NMMA in 5 AF patients and 7 normal controls (supine SBP 173±6 and 107±5 mmHg, respectively). Systolic blood pressure (SBP) was normalized to 110 mmHg in AF with graded head-up tilt, and baroreflexes were eliminated with trimethaphan in normal controls to mimic autonomic failure. The pressor response to graded doses of L-NMMA was shifted to the left in AF (Figure); The dose necessary to increase SBP by 30 mmHg was 3.4-fold lower in AF compared to controls (136±24 and 465±103 µg/kg/min respectively, p<0.02). In conclusion, contrary to our original hypothesis, our results suggest an increased tonic release of nitric oxide in AF. Thus, NO deficiency does not contribute to supine hypertension in autonomic failure. On the contrary, this enhanced tonic NO may contribute to orthostatic hypotension in these patients.



1413

Oral Administration of a Mineralocorticoid Receptor Antagonist Reduces Brain, Heart, and Blood-borne Proinflammatory Cytokines in Heart Failure

Yu-Ming Kang, Carver College of Med, Univ of Iowa, Iowa City, IA; Ralph F Johnson, Univ of Iowa, Iowa City, IA; Zhi-Hua Zhang, Carver College of Med, Univ of Iowa, Iowa City, IA; Robert M Weiss, Carver College of Med, Univ of Iowa and VA Med Ctr, Iowa City, IA; Alan K Johnson, Univ of Iowa, Iowa City, IA; Robert B Felder; Carver College of Med, Univ of Iowa and VA Med Ctr, Iowa City, IA

Introduction: Brain and blood-borne cytokines may contribute to neurohumoral excitation in heart failure (HF). We previously reported that blockade of mineralocorticoid receptors (MR) in the central nervous system with spironolactone (SL) reduces circulating tumor necrosis factor (TNF)-α in HF rats. The effect of SL on proinflammatory cytokines (PIC) in the brain and on other important circulating PIC - interleukin (IL)-1β and IL-6 - was not determined. **Hypothesis:** Chronic treatment with oral SL will reduce brain and blood-borne PIC in rats with HF following MI. **Methods and Results:** Rats underwent coronary artery ligation to induce MI (48.2±2.0% of left ventricle, with ejection fraction of 35.5±4.1% by echocardiography), or sham surgery (SHAM). Six weeks later, immunohistochemistry of the paraventricular nucleus (PVN) of hypothalamus, a region critical to cardiovascular regulation, revealed more PVN neurons (MI vs SHAM, **P<0.01) positive for TNF-α (59.5±3.3** vs 10.8±0.9) and IL-1β (70.7±3.9** vs 13.8±1.2) in MI (n=6) than in SHAM (n=6) rats. Double staining demonstrated that these neurons were distributed among PVN neurons expressing Fra-like immunoreactivity, indicating chronic neuronal activation. MI rats (n=6) treated with SL (1 mg/kg/day orally for 6 weeks) had fewer (MI+SL vs MI, #P<0.01) Fra-like positive PVN neurons (85.5±5.4# vs 183.8±5.0), and fewer PVN neurons positive for TNF-α (22.4±1.8#% vs 32.4±1.7%) and IL-1β (19.1±1.3#% vs 38.4±2.1%). Levels of TNF-α, IL-1β and IL-6 in brain and heart tissues and in plasma were also lower in MI rats treated with SL (see table). **Conclusion:** In rats with ischemia-induced heart failure, orally administered SL has a global inhibitory influence on the appearance of proinflammatory cytokines in brain, heart and plasma. The beneficial influence of MR antagonism in patients with HF may result at least in part from blocking aldosterone-induced cytokine synthesis. (Table: *P<0.05 MI+SL vs MI+VEH)

Group	plasma IL-1β (pg/ml)	plasma IL-6 (pg/ml)	heart IL-1β (pg/mg protein)	hypothalamus IL-1β (pg/mg protein)	hypothalamus TNF-α (pg/mg protein)	brainstem TNF-α (pg/mg protein)	brainstem IL-6 (pg/mg protein)	cortex IL-1β (pg/mg protein)	heart/BW (mg/g)	lung/BW (mg/g)
MI+VEH (n=7)	131.1±10.9	119.5±9.7	53.4±6.5	47.1±7.9	6.8±0.7	6.1±0.9	67.1±10.1	26.4±4.1	7.2±0.2	13.5±0.6
MI+SL (n=7)	57.5±3.1*	53.3±8.6*	32.6±5.9*	29.4±5.1*	3.8±0.6*	2.8±0.5*	39.4±5.5*	25.8±5.2	6.4±0.3*	12.1±0.6*
SHAM+SL (n=6)	48.2±3.6	33.7±2.8	23.7±6.5	17.4±4.8	2.8±0.7	2.1±0.6	25.3±4.8	24.3±4.9	3.3±0.1	5.2±0.3
SHAM+VEH (n=6)	53.9±2.4	36.1±2.6	27.6±5.4	18.8±4.0	3.2±0.9	2.4±0.8	28.0±8.7	23.6±6.5	3.4±0.1	5.1±0.3

Pulmonary Arterial Hypertension: New Therapies

Subspecialty: Integrative Biology
 Wednesday
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1414

Inhaled Treprostinil Sodium (TRE) For the Treatment of Pulmonary Hypertension

Robert Voswinckel, Beate Enke, Andre Kreckel, Frank Reichenberger, Stefanie Krick, Henning Gall, Tobias Gessler, Thomas Schmehl, Markus G Kohstall, Friedrich Grimminger, Hossein A Ghofrani, Werner Seeger, Horst Olschewski; Univ Hosp Giessen, Giessen, Germany

Objective: To evaluate the effects of inhaled TRE on pulmonary hemodynamics and gas exchange in severe pulmonary hypertension (PH) and to assess safety, tolerability and clinical efficacy in patients with severe PH. **Background:** TRE is a stable prostacyclin analogue that has been approved for treatment of pulmonary arterial hypertension as a continuous subcutaneous infusion. Iloprost, another prostacyclin analogue, has been shown to be efficacious in a randomised controlled study as repetitive inhalation. **Methods:** In an open-label study a preservative free solution of inhaled TRE was applied to 17 patients with severe pulmonary hypertension during Swan-Ganz catheter investigation. Patients received a TRE inhalation by use of the pulsed OptiNeb® ultrasound nebulizer (3 single breaths, TRE solution 600 µg/ml). Hemodynamics were observed for 2 hours. Two patients with idiopathic PAH received compassionate treatment with 4 inhalations of TRE per day after the acute test. **Results:** Patients (male/female= 4/13) suffered from iPAH (n=5), PAH other (n=8) and CTEPH (n=4); PVR 948 ± 112 dyn*cm⁻⁵, PAP 48.3 ± 2.7 mmHg, PAWP 8.9 ± 0.5 mmHg, CVP 10.8 ± 1.6 mmHg, CO 3.8 ± 0.3 l/min, SvO2 61.8 ± 1.8 %. TRE inhalation resulted in a sustained, highly pulmonary selective vasodilatation over 120 minutes. Maximum PVR decrease was -31.2 ± 4.5 % after 30 min. PVR and SVR at 120 minutes after inhalation were 89.2 ± 4.2 % and 101.0 ± 4.0 % of the baseline values, respectively. The AUC for the observation period (120min) was -22.9 ± 3.8 % for PVR and -4.9 ± 3.2% for SVR. The compassionate use patients have been treated for more than 3 months. In both patients NYHA class improved (from IV to III and from III to II), and six minute walk increased (from 0 m (bedridden) to 143 m, and from 310 m to 486 m, respectively). No side effects have been observed by the patients during long-term treatment. **Conclusion:** Inhaled TRE shows strong pulmonary selective vasodilatory efficacy with a long duration of effect following single acute dosing. Tolerability is excellent even at high drug concentrations and short inhalation times (3 breaths). Long-term treatment effects are very promising. The current results warrant controlled studies investigating this approach in a larger series of patients. Supported by Lung RX

1415

Rho-kinase In Pulmonary Hypertension

Ken Ishikura, Norikazu Yamada, Akihiro Tsuji, Satoshi Ota, Mashio Nakamura, Masaaki Ito, Naoki Isaka, Takeshi Nakano; Mie Univ Sch of Med, Tsu, Japan

Objectives: Pulmonary hypertension (PH) is a poor prognostic disease with limited treatment. Rho-kinase is involved in the pathophysiology of several diseases underlying smooth muscle hypercontraction. But the role of it is unknown. The purpose of this preliminary report was to indicate the efficacy of fasudil, a Rho-Kinase inhibitor in patients with pulmonary hypertension using interventional hemodynamic assessment. **Methods:** Fasudil was intravenously injected in 10 patients (9 female, mean ± SD, 46 ± 15 years, NYHA II n=2, III n=7, IV n=1) with primary (n=5) and secondary (n=5) PH who were not received any vasodilator. Fasudil was administered 30mg with 1mg/min. Hemodynamic data were measured using Swan-Ganz catheter until 60 minutes after starting administration of fasudil. Hemodynamic and arterial blood gas data of baseline and the lowest total pulmonary resistance (TPR) time were compared. **Results:** The lowest TPR time was within 30 to 60 minutes after administration. Administration of fasudil significantly decreased TPR from 13.6 ± 6.8 U to 10.3 ± 4.9 U (-23.2 ± 9.2 %, p < 0.001) and mean pulmonary arterial pressure (mPAP) from 43.6 ± 14.5 mmHg to 38.8 ± 13.9 mmHg (-11.6 ± 10.4 %, p < 0.02). Cardiac index (CI) was significantly increased from 2.39 ± 0.66 L/min/m² to 2.74 ± 0.73 L/min/m² (+16.5 ± 15.1 %, p < 0.01). Although TPR was equally decreased in both primary and secondary PH, the changes in the parameters that prescribed TPR, namely CI and mPAP, were different between the two groups subjects. Increased CI was a major factor into reducing TPR in primary PH, while reduced mPAP

EXHIBIT E



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Legend

Every abstract is identified as either "BENCH" or "BEDSIDE".

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218 Inhaled treprostinil is a potent pulmonary vasodilator in severe pulmonary hypertension



R. Voswinckel, M.G. Kohstall, B. Enke, T. Gessler, F. Reichenberger, H.A. Ghofrani, W. Seeger, H. Olschewsky. *Medical Clinic 2, Department of Internal Medicine, Giessen, Germany*

Background: Treprostinil has been approved for therapy of PAH (US and Canada) as continuous subcutaneous infusion. However, local pain at the infusion site is a major drawback. Inhaled therapy with another stable prostacyclin analogue (iloprost) has been approved for PPH (EMA). In this study we investigated the acute hemodynamic response to inhaled treprostinil.

Methods: Open-label, single blind placebo-controlled clinical study. After placement of a Swan-Ganz catheter and a femoral artery line, patients inhaled solvent solution (placebo) (n=8) or treprostinil for 6 min (OptiNeb ultrasound nebulizer, Nebu-tec, Germany) in concentrations of 16, 32, 48, and 64 µg/ml (n=6, 6, 6, and 3 patients). Measurement was performed before and after 0, 15, 30, 60, 90, 120, 150 and 180 min. The mean area between the placebo and the treprostinil curves (ABC186) was calculated (baseline=100%).

Results: We investigated idiopathic PAH (n=10), collagen vascular disease (n=5), chronic thromboembolic disease (n=9), and pulmonary fibrosis (n=5), f/m = 19/10, age 56 ± 3 years, PAP, PAWP, and CVP 51.3 ± 2.2, 9.2 ± 0.8, and 6.6 ± 0.6 mmHg, CO 4.4 ± 0.3 l/min, SvO₂ 62.3 ± 1.2%, PVR 885 ± 72 dyn s cm⁻⁵. At 16µg/ml there were no significant adverse events. Headache, cough or bronchoconstriction were observed in 2, 1, and 2 patients at 32, 48, and 64 µg/ml. These were mild and transient in all patients but one (64 µg/ml) who complained of major headache for 1 hour. Placebo inhalation was followed by slowly increasing PVR. Compared to this, the maximum treprostinil effect was reached after about 50 min and half-maximal effects at about 110 min. The ABC186 for PVR was -24.7 ± 4.4, -28.7 ± 4.9, and -29.0 ± 4.7%; PAP -14.4 ± 3.3, -13.5 ± 5.2, -13.1 ± 2.6%; SAP -5.1 ± 3.0, -6.0 ± 3.1, -3.8 ± 2.1% at 16, 32 and 48 µg/ml.

Conclusion: Treprostinil inhalation results in a significant long-lasting pulmonary vasodilatation. With the applied technology, at a concentration of 16µg/ml, near maximal pulmonary vasodilatation is achieved without adverse effects. At higher doses, local and systemic side effects may occur, whereas pulmonary selectivity is preserved.

This study was supported by Lung Rx.

219 The endothelin-receptor antagonist bosentan for the treatment of pulmonary arterial hypertension associated with congenital heart defects



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Background: Treatment with the oral dual endothelin-receptor antagonist bosentan has been shown to be an effective alternative option to intravenous epoprostenol in functional class (FC) III idiopathic pulmonary arterial hypertension (PAH) patients. In patients with PAH associated with congenital heart defects (CHD), an improvement of exercise capacity and hemodynamics has been demonstrated with epoprostenol in one uncontrolled study (Rosenzweig et al. *Circulation* 1999; 99: 1858-65).

The aim of this retrospective study was to evaluate the efficacy and safety of bosentan in FC III-IV CHD-PAH patients.

Study population consisted in 24 patients (22 females, mean age 35 ± 15 years [8-68]) with CHD-PAH: atrial septal defect (ASD: 13), ventricular septal defect (VSD: 4), partial abnormal pulmonary venous return (3, associated with ASD in 2 and repaired common atrium in 1), patent ductus arteriosus (PDA: 2), VSD associated with PDA (1), aortopulmonary window (1). Four patients had undergone previous cardiac surgery.

Patients had deteriorated despite conventional therapy (including oral anticoagulants, oxygen, diuretics) and were treated with chronic oral bosentan.

Results: Before starting bosentan, 22 patients were in FC III and 2 in FC IV, with a resting O₂ saturation (SaO₂) of 89 ± 9%. Mean 6-min walk distance (6MWD) was 288 ± 94 m and mean Borg index 3.0 ± 1.9. At last evaluation performed after 10 ± 9 months of bosentan treatment, 1 patient was in FC I, 8 were in FC II, 13 remained in FC III and 2 in FC IV. The mean 6MWD improved by 49 m (349 ± 85 m, p = 0.008) with no change in Borg index (3.0 ± 1.8) and resting SaO₂ (89 ± 6%). There were no differences between pre and post-tricuspid shunt subgroups in terms of baseline characteristics and response to bosentan therapy. After 13 ± 9 months of follow-up, all patients are alive on bosentan, but 3 (1 ASD, 1 VSD, 1 aortopulmonary window) required combination therapy with intravenous epoprostenol after 5, 7 and 9 months on bosentan.

Conclusion: Chronic oral bosentan treatment improves exercise capacity in patients with PAH associated with CHD who deteriorated despite conventional therapy. Bosentan had no adverse effect on arterial oxygen saturation. As previously demonstrated in patients with idiopathic PAH, long term bosentan may be an important therapeutic option for patients with PAH associated with CHD.

220 Sildenafil in the treatment of primary pulmonary hypertension



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Background: The role of sildenafil as a pulmonary vasodilator is being extensively evaluated in the treatment of pulmonary hypertension.

Aim: This was a prospective study to assess the benefit of adding sildenafil in patients with high pulmonary artery pressures secondary to atrial septal defect (ASD), already receiving the conventional therapy.

Methods: Thirty consecutive patients with moderate to severe primary pulmonary hypertension were included in this study. All the patients were diagnosed previously and were receiving the conventional therapy with digoxin, diuretic and a calcium channel blocker. Sildenafil was added in the dose of 50 mg twice a day without changing the previous regimens. Changes in the New York Heart Association (NYHA) symptom class, distance covered during the six minute walk test and modified Borg dyspnea score were evaluated monthly. Acceptance of the new drug was assessed every week in the first month and then at the monthly follow up. Echocardiography and Doppler study was undertaken at baseline and every month for a period of six months. The parameters studied were the pulmonary artery systolic pressure (PASP) by tricuspid regurgitation (TR) jet and pulmonary artery diastolic pressure (PADP) by pulmonary regurgitation (PR) jet.

Results: Mean age of the subjects was 42.6±9.3 years. Twenty seven (90%) were females and 3 (10%) were males. Sildenafil was well tolerated and there was no dropout because of undesirable effects of the drug. Changes in the heart rate and systemic blood pressure were not significant enough to warrant withdrawal of the drug. Two patients died during the follow-up period. At the beginning of the therapy, 22 (73.3%) patients were in NYHA Class III or IV while at the end of six months, only 8 patients remained in either of these classes (p<0.05). By the 6 min walk test, functional capacity improved from 181.5±122.4 meters to 302.7±150.3 meters (p<0.05). Modified Borg dyspnea score improved from 5.6±1.2 to 3.3±1.1 (p<0.05). PASP by TR jet (mmHg) was down from 81.3±14.7 to 51.4±11.7 (p<0.05). PADP by PR jet (mmHg) reduced from 56.2±11.7 to 33.4±9.1 (p<0.05).

Conclusion: Sildenafil is well tolerated, improves symptoms, and reduces the systolic and diastolic pulmonary artery pressures in patients with moderate to severe primary pulmonary arterial hypertension.

REVISITING THE ELECTROCARDIOGRAM AND ELECTROPHYSIOLOGIC MARKERS OF ARRHYTHMIC EVENTS

221 Prevalence of brugada-type ecg in an apparently healthy european population



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Background: The Brugada Syndrome ECG is characterized by ST-segment elevation in right precordial leads and elevated risk of lethal arrhythmias in absence of identifiable structural heart disease. Few data are available on the Brugada type ECG, especially in Europeans. No epidemiological study has applied the diagnostic criteria recently proposed by the Study Group of the Molecular Basis of Arrhythmias of the ESC.

Methods: We analysed the ECG and clinical data of apparently healthy European adults undergoing routine medical examinations for occupational reasons. At each examination subjects underwent a medical interview, physical examination, blood pressure measurement and 12-lead ECG. Enrolment was confined to persons without a history of heart disease at the time of first attendance in whom at least one 12-lead ECG of good quality was recorded. The ECG records of all 7483 subjects (89.6% male, age 29.5±10.8 years at first attendance) were reviewed by three cardiologists. We reviewed 1,97±2.1 ECGs for each subject. We considered a patient having a Brugada ECG pattern if 2 or more of the cardiologists judged that at least one of that persons ECGs fulfilled the criteria of the ESC Study Group.

Results: The Brugada pattern was present in 26 patients (0.35%), all male (table). In 17 cases (65.4%), information was available about the progress of the subject subsequent to the ECG on which the Brugada pattern was first recorded. No sudden death or cardiac arrhythmia was recorded among these patients in a follow-up of 5.2±4.6 years (total follow-up 87.8 patient-years).

	Total	Pattern 1	Pattern 2	Pattern 3	Tot. Brugada
Pts (n)	7383	2	21	3	26
Male	6618	2	21	3	26
Female	765	0	0	0	0
Male prevalence (*10000)	-	3.02	31.73	4.53	39.29
Total Prevalence (*10000)	-	2.71	28.44	4.06	35.22

EXHIBIT F

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Exercise Is Associated with Reduced Risk for Incident Dementia among Persons 65 Years of Age and Older 73

E.B. Larson, L. Wang, J.D. Bowen, W.C. McCormick, L. Teri, P. Crane, and W. Kukull

The authors followed 1740 persons who did not have cognitive impairment at baseline. During a mean follow-up of 6.2 years, 158 participants developed dementia; the incidence rate was 13.0 per 1000 person-years for those who exercised 3 or more times per week at baseline and 19.7 per 1000 person-years for those who exercised less frequently. The results were similar in the 107 participants who developed Alzheimer disease.

Summary for Patients 1-20

Socioeconomic Status and Mortality after Acute Myocardial Infarction 82

D.A. Alter, A. Chong, P.C. Austin, C. Mustard, K. Iron, J.I. Williams, C.D. Morgan, J.V. Tu, J. Irvine, and C.D. Naylor, for the SESAMI Study Group

The true causes of income-related health disparities are not known. In 3407 Canadian patients who were hospitalized for acute myocardial infarction, high income was associated with a lower 2-year mortality rate (crude hazard ratio, 0.45 [95% CI, 0.35 to 0.57]; $P < 0.001$). However, adjusting for income-related differences in age and the prevalence of preexisting cardiovascular events or risk factors substantially reduced the effect of high income (adjusted hazard ratio, 0.77 [CI, 0.54 to 1.10]; $P = 0.150$).

Summary for Patients 1-42

Clarithromycin-Resistant Genotypes and Eradication of *Helicobacter pylori* 94

V. De Francesco, M. Margiotta, A. Zullo, C. Hassan, L. Troiani, O. Burattini, F. Stella, A. Di Leo, F. Russo, S. Marangi, R. Monno, V. Stoppino, S. Morini, C. Panella, and E. Ierardi

The authors compared *Helicobacter pylori* eradication rates among strains with different point mutations that confer clarithromycin resistance. Antibiotics eradicated *Helicobacter pylori* infection in 11 of 23 patients (48%) with the A2143G mutation and in 14 of 15 patients (93%) with either A2142G or A2142C strains. A sequential triple-therapy regimen achieved a higher cure rate than simultaneous triple therapy in A2143G mutation strains.

Brief Communication: Tamoxifen Therapy for Nonmalignant Retroperitoneal Fibrosis 101

E.F.H. van Bommel, T.R. Hendriksz, A.W.L.C. Huiskes, and A.G.M. Zeegers

Retroperitoneal fibrosis is a progressive disease that can respond to corticosteroids but is sometimes steroid-resistant. Among 19 patients with retroperitoneal fibrosis who received tamoxifen, 20 mg twice daily, 15 reported substantial symptom resolution after a median of 2.5 weeks. Repeated computed tomography showed mass regression in 14 of 15 clinical responders. Treatment failed in 5 patients, and 1 patient developed severe hepatitis while receiving treatment.

Summary for Patients 1-51

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Problem Doctors: Is There a System-Level Solution? 107

L.L. Leape and J.A. Fromson

Three ideas frame an effective system for managing poorly performing physicians: Subpar performance can be objectively defined; routine monitoring of the entire medical staff is necessary to detect problems fairly and early; and responses to deficiencies should be prompt, constructive, and sustained. The long-term objective is to enable physicians to continue to practice effectively and safely, not to "weed them out."

REVIEW

Systematic Review: Antimicrobial Urinary Catheters To Prevent Catheter-Associated Urinary Tract Infection in Hospitalized Patients 116

J.R. Johnson, M.A. Kuskowski, and T.J. Wilt

The authors assessed the efficacy of currently marketed antimicrobial urinary catheters. In this systematic review of 12 trials, they concluded that antimicrobial urinary catheters can prevent bacteriuria in hospitalized patients during short-term catheterization. The cost implications of these catheters and their effect on infectious complications remain undefined.

PERSPECTIVE

Acute Pain Management for Patients Receiving Maintenance Methadone or Buprenorphine Therapy 127

D.P. Alford, P. Compton, and J.H. Samet

The number of patients with opioid addiction who receive opioid agonist therapy (OAT) with methadone and buprenorphine is increasing, so that physicians will more frequently encounter such patients who have acutely painful conditions. This paper acknowledges the complex interplay

Continued on page 1-6

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I-5

among addictive disease, OAT, and acute pain management; describes 4 misconceptions that lead to suboptimal treatment of acute pain; and gives clinical recommendations for providing analgesia when a patient receiving OAT develops acute pain.

EDITORIALS

Mens Sana in Corpore Sano 135

L.J. Podewils and E. Guallar

Larson and colleagues provide important evidence that more physical exercise is associated with lower rates of dementia, adding significantly to several other recent studies on the association between physical activity and dementia risk. We now need randomized trials to examine the effect of physical activity on cognitive function measures, and we need researchers to include clinical dementia end points in ongoing trials of lifestyle modification.

Going Back To Understand the Future: Socioeconomic Position and Survival after Myocardial Infarction 137

G.A. Kaplan

Do we really need another paper on socioeconomic inequalities in health? Alter and colleagues have added to our knowledge, but the assumption that we can reduce socioeconomic inequalities in survival after cardiovascular disease (CVD) by reducing morbidity and risk factors in poor people begs the key question. We must integrate our knowledge of the upstream social determinants that lead to differential burdens of CVD and its risk factors and the downstream, proximal biological factors that drive health outcomes. Building a bridge between these bodies of knowledge could provide a way to decrease socioeconomic inequalities in survival.

Improving *Helicobacter pylori* Eradication Regimens 140

F. Francois and M.J. Blaser

The work by De Francesco and colleagues showing the enhanced efficacy of sequential therapy is a timely advance for patients with peptic ulcer disease or mucosa-associated lymphoid tissue lymphoma, in whom *Helicobacter pylori* eradication is clearly indicated. A larger question is whether the relatively indiscriminate practice of "test and treat" for *H. pylori* infection treats the patient or the physician. In their zeal to remedy many ailments with antibiotics, physicians are contributing to new problems of antibiotic resistance and to changing human microecology.

ON BEING A DOCTOR

Of Poems and Patients 142

D. Seder

Recently, my wife and I were out listening to a folk singer, and I realized how hard it is to listen to live music without leaning across a bar. It wasn't so long ago that 4 or 5 nights a week I poured beer and shook drinks while customers came and went. That life is so different from my current one that it could have been led by another person entirely.

Aziza 143

R. Kannai

During the physical examination, Aziza read me with astute observation: She sensed my aversion to physical contact with her and my attempt to end the session peacefully. I tried to understand the contents of her thoughts, since she easily transferred from the world of delusions to our world, complete with National Insurance forms. Why couldn't I, the sane one, identify with her hallucinations?

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National Health Information Network Cost and Structure 145

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Exorcising Ghosts and Unwelcome Guests

TO THE EDITOR: We applaud the editors of *Annals* for their effort to increase awareness regarding ghostwriting (1). Drs. Laine and Mulrow cite our editorial (2), but a slight correction is needed; they imply that the GATE principles were proposed by the European Medical Writers Association. Actually, we initially proposed these guidelines ourselves in our editorial (2). However, we were influenced by the association's statements and by our own experience when we formulated these guidelines.

There is increasing concern about ghostwriters because it is difficult to prove their existence. Therefore, whenever help from professional writers is necessary, it is imperative that the GATE principles are maintained. Maybe a uniform policy should be implemented by journals (in our editorial, we proposed a formula of acknowledgment statements to achieve maximum transparency). One key issue not addressed by Laine and Mulrow is the possibility of regulating professional writers. In other words, writers would need to be registered and evaluated to maintain minimum standards (2).

The earliest article on ghostwriting that we identified through a search of PubMed was published in 1934 (3). It is about time that we sort out this issue. Professional writers, if they have to be used, should have a legitimate role in assisting (not replacing) experts to provide a quality document while maintaining high ethical standards. However, the experts should always play a key role and have

the final say on content. Hidden ghosts, unwelcome guests, and hired experts do not have any place in the medical literature.

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Potential Financial Conflicts of Interest: None disclosed.

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3. Place F. Ghost writing. *Bull Med Libr Assoc*. 1934;22:209-213. [PMID: 16016210]

TO THE EDITOR: I was pleased to read Drs. Laine and Mulrow's editorial about ghosts and guests, which I thought steered a very sensible course through a difficult topic (1). I feel that 1 minor point of clarification is required, however. The GATE principles referred to in the editorial were not described by the European Medical Writers Association but were described in an editorial (2) that accompanied the association's guidelines. Readers of *Annals* may also be interested in the original guidelines (3), which were not cited by Drs. Laine and Mulrow in their editorial.

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Potential Financial Conflicts of Interest: Dr. Jacobs is a former president of the European Medical Writers Association and is a coauthor of the association's guidelines on the role of medical writers in developing peer-reviewed publications.

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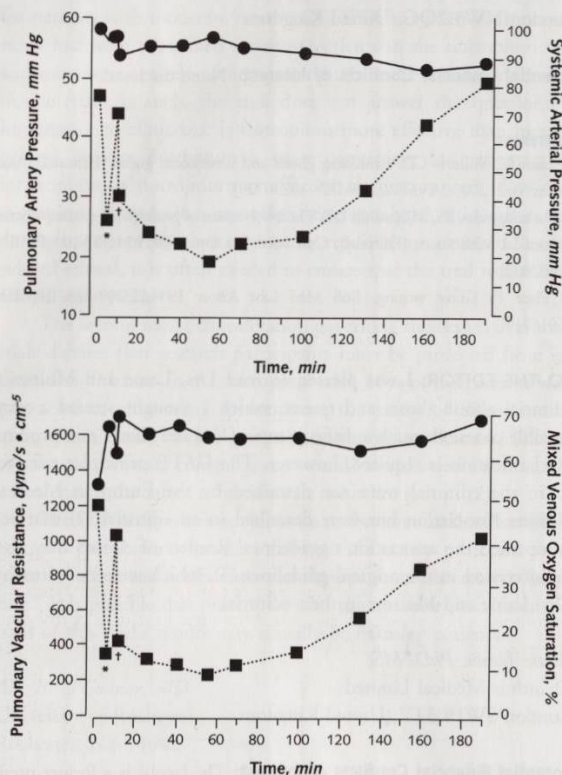
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CLINICAL OBSERVATIONS

Inhaled Treprostinil for Treatment of Chronic Pulmonary Arterial Hypertension

TO THE EDITOR: *Background:* Treprostinil is a stable prostacyclin analogue that is approved for the treatment of pulmonary arterial hypertension when administered by continuous subcutaneous infusion (1). Inhalation of the stable prostacyclin analogue iloprost has

Figure. Acute hemodynamic response of a patient with idiopathic pulmonary arterial hypertension to the inhalation of nitric oxide (20 parts per million) and 15 μ g of treprostinil.



Asterisks indicate administration of nitric oxide, and daggers indicate administration of treprostinil. Pulmonary artery pressure was substantially reduced with nitric oxide and even further reduced with treprostinil (top, squares). Systemic arterial pressure was not affected by either substance (top, circles). Pulmonary vascular resistance was substantially reduced with nitric oxide and even further reduced with treprostinil; the effect of treprostinil outlasted the observation time of 180 minutes (bottom, squares). Long-lasting improvement of mixed venous oxygen saturation represented improved cardiac output in absence of gas exchange deterioration (bottom, circles).

proven clinical efficacy in patients with pulmonary hypertension in a randomized, controlled trial (2).

Objective: To characterize the effects of inhaled treprostinil with special regard to safety, tolerability, and efficacy in patients with severe pulmonary arterial hypertension.

Methods and Findings: Three patients with severe pulmonary hypertension underwent catheterization of the right heart and femoral artery for evaluation of pulmonary and systemic hemodynamics. The protocol consisted of assessment of baseline values; administration of nitric oxide at a concentration of 20 parts per million; and administration of a single 15- μ g dose of treprostinil, inhaled in 3 breaths through a modified OptiNeb ultrasonic inhalation device (Nebu-Tec, Elsenfeld, Germany). All 3 patients had severe pulmo-

nary hypertension; mean pulmonary vascular resistance (\pm SE) was 1355 ± 286 dyne/s per cm^{-5} . Inhalation of nitric oxide resulted in a mean reduction (\pm SE) in pulmonary vascular resistance of $26\% \pm 22.8\%$. Inhalation of treprostinil substantially reduced pulmonary vascular resistance (mean maximum change [\pm SE], $-45.2\% \pm 17.5\%$) for a sustained period (duration of effect, >180 min). Pulmonary selectivity of the approach was reflected by a substantially reduced ratio of pulmonary vascular resistance to systemic vascular resistance; the mean area under the curve (\pm SE) was $30\% \pm 11\%$ for pulmonary resistance and $16\% \pm 3\%$ for systemic resistance. One patient had a favorable vasodilator response (shown in the Figure) and was therefore given high-dose calcium-channel blocker therapy.

The other 2 patients were offered long-term inhaled treprostinil therapy (on a compassionate treatment basis), consisting of 4 daily 15- μ g doses. Over the first 3 months of treprostinil therapy, the functional status of both patients improved dramatically (New York Heart Association class improved from IV to III and from III to II, respectively; 6-minute walking distance increased from 0 to 143 m and from 310 to 486 m, respectively). No side effects were observed.

Conclusion: In this preliminary report, single applications of inhaled treprostinil induced highly pulmonary selective and sustained vasodilatation. The drug was clinically effective, safe, and well tolerated when 15 μ g was inhaled in 3 breaths 4 times daily. The current results warrant controlled studies to investigate this approach in a larger group of patients.

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Neurocysticercosis in Kansas

TO THE EDITOR: *Background:* In the United States, neurocysticercosis is a disease that is most often identified in persons of Hispanic ethnicity. Cases of the disease have been reported from large urban areas (1); however, no studies have evaluated neurocysticercosis in rural areas.

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rehabilitation:Cardiac Rehabilitation

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MARC Bibliographic Record

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222 _0 \$aCirculation

245 00 \$aCirculation :\$bthe journal of the American Heart Association.

260 \$aNew York :\$bGrune & Stratton,\$c1950-

300 \$avolumes :\$billustrations ;\$c28 cm

310 \$a14 no. a year\$b<Nov. 1979->

321 \$aMonthly

336 \$atext\$btxt\$2rdacontent

337 \$aunmediated\$bn\$2rdamedia

338 \$avolume\$bnc\$2rdacarrier

362 0_ \$aVol. 1, no. 1 (Jan. 1950)-

500 \$aThe journal of the American Heart Association.

555 \$aVols. 1-52, 1950-75. 1 v.

530 \$aAlso available on the Internet.

525 \$aIncludes supplements; [1993]- supplements for each vol. are consecutively numbered.

650 _0 \$aCardiology\$xSocieties.

650 _0 \$aHeart\$xDiseases\$VPeriodicals.

650 _2 \$aBlood Circulation\$Vperiodicals.

650 _2 \$aCardiovascular System\$Vperiodicals.

710 2_ \$aAmerican Heart Association.

997 \$aMARCIVE

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 222 _0 \$aCirculation\$b(Online)
 245 10 \$aCirculation

- 246 33 \$aJournal of the American Heart Association
- 260 \$a[Baltimore, Md.] :\$bLippincott Williams & Wilkins ;\$a[Stanford, Calif.] :\$bHighwire Press
- 336 \$atext\$btxt\$2rdacontent
- 337 \$acomputer\$bc\$2rdamedia
- 338 \$aonline resource\$bcr\$2rdacarrier
- 362 1_ \$aPrint began in 1950.
- 500 \$aRefereed/Peer-reviewed
- 506 \$aLimited access, restrictions may apply.
- 538 \$aMode of access: World Wide Web.
- 588 \$aDescription based on: Vol. 91, no. 1 (Jan. 1995); title from home page.
- 650 _0 \$aBlood\$xCirculation\$vPeriodicals.
- 650 _0 \$aCardiovascular system\$vPeriodicals.
- 650 _0 \$aCardiology\$vPeriodicals.
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710 2_ \$aAmerican Heart Association.

906 \$aJOURNAL

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MARC Display		Labelled Display		

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- 053 _0 |a AS |c Academies and learned societies
- 053 _0 |a HS |c Associations, secret societies, clubs
- 150 __ |a Societies
- 360 __ |i subdivision |a Societies, etc. |i under names of individual persons, families, and corporate bodies, and under classes of persons, ethnic groups, uniform titles of sacred works, and topical headings; also subdivision |a Societies and clubs |i under age and sex groups; and names of individual societies
- 450 __ |a Academies (Learned societies)
- 550 __ |w g |a Associations, institutions, etc.
- 550 __ |a Clubs
- 906 __ |t 0316 |u te04 |v 0
- 953 __ |a xx00 |b ta27

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LCCN Permalink: <https://lcn.loc.gov/sh2009126258>

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090 \$b

210 0 Circulation \$b (N.Y.N.Y.)

222 0 Circulation \$b (New York, N.Y.)

245 00 Circulation.

260 [Dallas, Tex., etc.], \$b [American Heart Association, etc.]

300 volumes \$b illustrations \$c 28 cm

310 Weekly (except the first two weeks in Jan. and the last two weeks in Dec.), \$b <Apr. 8, 2003-

321 Monthly, \$b 1950-

336 text \$b txt \$2 rdacontent

337 unmediated \$b n \$2 rdamedia

338 volume \$b nc \$2 rdacarrier

362 0 v. 1- Jan. 1950-

510 2 Chemical abstracts \$x 0009-2258

525 Has annual supplements with titles: Cardiovascular surgery, 1962-, and: Abstracts, 1964- ; also has occasional additional supplements.

525 Supplements for 1962-63 and <1982 lack "supplement" in title.
 525 Supplements for 1987- also called: Circulation monograph, no. 1-
 555 Vols. 1-52, 1950-75. 1 v.
 580 Some supplements also issued as: American Heart Association monograph, 1962-85; and,
 Monograph (American Heart Association), 1986.
 580 Includes: Hypertension, v. 12 (published as Aug. 1964 supplement), which is also available
 separately.
 588 Latest issue consulted: Vol. 107, no. 14 (Apr. 15, 2003).
 650 0 Cardiology \$v Periodicals.
 650 0 Cardiovascular system \$v Periodicals.
 650 0 Hypertension \$v Periodicals.
 650 2 Blood Circulation \$x periodicals.
 650 2 Cardiovascular System \$x periodicals.
 650 6 Cardiologie \$v Périodiques.
 650 6 Sang \$x Circulation \$v Périodiques.
 650 6 Appareil cardiovasculaire \$v Périodiques.
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LCCN Permalink: <https://lcn.loc.gov/sh85020226>

HEADING: Cardiovascular system

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- 053 _0 |a QL835 |b QL841 |c Comparative anatomy
- 053 _0 |a QM178 |b QM197 |c Human anatomy
- 150 __ |a Cardiovascular system
- 360 __ |i subdivision |a Cardiovascular system |i under individual animals and groups of animals, e.g. |a Fishes--Cardiovascular system
- 450 __ |a Circulatory system
- 450 __ |a Vascular system
- 550 __ |a Blood |x Circulation
- 906 __ |t 8751 |u fk03 |v 0
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LCCN Permalink: <https://lccn.loc.gov/sh85099890>

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053 _0 |a AP |c General periodicals

053 _0 |a PN4700 |b PN5650 |c History

150 __ |a Periodicals

360 __ |i subdivision |a Periodicals |i under specific subjects, e.g. |a Engineering--Periodicals; United States--History--Periodicals

450 __ |a Journals (Periodicals)

450 __ |a Magazines

550 __ |w g |a Library materials

550 __ |w g |a Mass media

550 __ |w g |a Serial publications

550 __ |a Newspapers

550 __ |a Press

670 __ |a UMI business vocab. |b (Journals)

680 __ |i Here are entered works on the periodicals of the world and, with appropriate subdivisions, works on special aspects or sections of periodicals. Works on periodicals in a specific language, or in a specific country or larger area, are entered under the adjectival form of the language or area, e.g. |a Arabic periodicals; Canadian periodicals.

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910 __ |a Proposal saved by tc03 on 05/14/2012 at 17:15:30

953 __ |a xx00 |b td14

906 __ |t 1206 |v 0

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LCCN Permalink: <https://lcn.loc.gov/sh85063723>

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- 450 __ |a Vascular hypertension
- 550 __ |w g |a Blood circulation disorders
- 906 __ |t 9106 |u fk07 |v 1
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 362 0#\$av. 1- Feb. 1980-
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 530 ##\$aAvailable also online to subscribers.
 550 ##\$aOfficial journal of the European Society of Cardiology.
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776 0#\$tEuropean heart journal (Online)\$x1522-9645

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060 00 W1 \$b EU636
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210 0 Eur. heart j.
222 0 European heart journal
245 00 European heart journal.
260 Amsterdam, \$b Elsevier.
300 volumes \$b illustrations \$c 28 cm
310 Semimonthly, \$b <2004-
321 Bimonthly, \$b <-1982
321 Monthly, \$b <1983-
336 text \$b txt \$2 rdacontent
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338 volume \$b nc \$2 rdacarrier
362 0 v. 1- Feb. 1980-
500 Published: Oxford ; New York : Pergamon Press, 1988- ; Oxford : Oxford University Press, 2005-
510 2 Chemical abstracts \$x 0009-2258
525 Vols. for 19<80-1998 include irregularly issued supplements.
550 Official journal of the European Society of Cardiology.
580 Companion publication to: European heart journal. Cardiovascular pharmacotherapy.
580 Companion journal to: European heart journal. Quality of care & clinical outcomes.
650 0 Cardiology \$v Periodicals.
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210 0_ \$aAnn. intern. med.
222 _0 \$aAnnals of internal medicine
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- 260 \$aAnn Arbor, Mich. :\$bAmerican College of Physicians.
- 300 \$avolumes :\$billustrations ;\$c25-28 cm
- 310 \$aMonthly
- 336 \$atext\$btxt\$2rdacontent
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- 362 0_ \$a[Vol. 1, no. 1 (July 1927)]-
- 530 \$aIssued also in electronic format.
- 555 \$aVols. 1-40, July 1927-June 1954, 1 v., vols. 41-50, June 1954-June 1959, 1 v.
- 515 \$aVol. 2-71 called also old ser. v. 7-74
- 550 \$aOfficial publication of: American College of Physicians.
- 580 \$aHas supplement: 1991- ACP journal club.
- 650 _0 \$aMedicine\$vPeriodicals.
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- 710 2_ \$aAmerican College of Physicians.
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- 245 10 \$aAnnals of internal medicine.
- 246 3_ \$aAnnals.org
- 260 \$a[Philadelphia, Pa.] :\$bAmerican College of Physicians
- 310 \$aSemimonthly
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- 338 \$aonline resource\$bcr\$2rdacarrier
- 362 1_ \$aPrint began with vol. 1 (July 1927).
- 500 \$aRefereed/Peer-reviewed
- 515 \$aVol. 2-[50] called also old ser. v.7-[55].
- 515 \$aIssues for [1991-] consist of 2 vols. per year with 12 nos. each.
- 580 \$aHas supplement: ACP journal club, 1991-94; which became an independent publication in 1995.
- 588 0_ \$a15 July 1997.
- 588 1_ \$aVol. 172, issue 7 (Apr. 7, 2020) (annals.org, viewed Apr. 19, 2020).
- 650 _0 \$aMedicine\$vPeriodicals.
- 650 _2 \$aInternal Medicine.
- 650 _2 \$aMedicine.

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222 0 Annals of internal medicine

245 00 Annals of internal medicine.

260 [Philadelphia, etc.], \$b [American College of Physicians]

300 volumes \$b illustrations, diagrams \$c 26 cm

310 Semimonthly, \$b <1991-
 321 Monthly, \$b 1927-
 336 text \$b txt \$2 rdacontent
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 362 0 v. 1- July 1927-
 510 2 Chemical abstracts \$x 0009-2258
 515 Vol. 2-<50 called also old ser. v. 7-<55
 515 Issues for <1991- consist of 2 vols. per year with 12 nos. each.
 555 Vols. 1-40, July 1927-June 1954. 1 v.; Vols. 41-50, June 1954-June 1959. 1 v.
 580 Has supplement: ACP journal club, 1991-1994; which became an independent publication in 1995.
 580 Absorbed ACP journal club as a section and continues its own volume numbering with v. 148, no. 3
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