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History of Pharmacy SIG

Pharmacy Chronicles: Past, Present, and Future

Welcome Message from the Chair, History of Pharmacy Special Interest Group

"One natural bridge between the humanistic and the technical is formed by the profession's own history, which seems to be essential to an adequate understanding and philosophy of the pharmacist's role in society."

--Glenn Sonnedecker (Preface to Kremers and Urdang's History of Pharmacy)

As someone trained in social and administrative pharmacy and who identifies as a social scientist, I have long been drawn to the humanistic aspects of the profession. My interest in history comes from its explanatory potential, especially the power of individual and collective stories to show how pharmacy's ideas, values, and practices have evolved. I am excited and honored to serve as SIG Chair this year, and this perspective shapes how I approach the SIG's work and our efforts to support engagement, learning, and collaboration within AACP. This year, the SIG will focus on aligning with AACP strategic goals while advancing initiatives that strengthen scholarship, teaching, and community in the history of pharmacy.

We welcome new SIG members and introduce new leadership, including Wesley Sparkmon as Chair-Elect. Our priority SIG areas emphasize collaboration and engagement. For example, in partnership with the American Institute of the History of Pharmacy (AIHP), we will continue to promote initiatives such as the Virtual Historical Markers of Pharmacy & Pharmaceuticals Across North America, the Monthly Pharmacy History Working Group, and the PharmD History of Pharmacy Fellowship. Details and links are available on the AACP Connect discussion board.

Committee work remains central to SIG activities. The Newsletter Committee, co-chaired by Bernie and Megan, will continue producing peer-reviewed issues. Additionally, we will explore options to expand the newsletter to a digital platform to improve accessibility and create a searchable archive of past content. Programming will focus on offering a SIG session at the AACP Annual Meeting and a webinar later in the year. Teaching initiatives will be revisited, especially where there are opportunities for growth. In collaboration with the Assessment SIG, we will update a list of history contacts across AACP member colleges to serve as a shared resource for outreach and

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INSIDE THIS ISSUE:

Meet the Editors

Editor

Megan R. Undeberg Pharm.D., BCACP
Clinical Professor
Washington State University,
College of Pharmacy
HSB 210 n
PO Box 1495
Spokane, WA 99210
Tel. 509-979-2456
mail: meganru@wsu.edu

Editor

Bernie R. Olin, Pharm.D.
Associate Clinical Professor
Auburn University, Harrison College of Pharmacy
362 W. Thach Concourse
2211D Walker Building
Auburn, AL 36849
Tel. 334.844.8334
E-mail: olinber@auburn.edu

THANK YOU!

The Editors would like to thank the volunteers who performed the peer reviews and editing for this issue.

Michelle Bottenberg
Marilyn Bulloch
Lee Evans
Robert Cisneros
Paul Jungnickel
Jane Krause
Karen Nagel-Edwards
Wes Sparkman
Cathy Taglieri

Message from the Editor

Welcome!

We are pleased to present the 19th issue in our 12th year of publishing, of the History of Pharmacy SIG Newsletter *Pharmacy Chronicles: Past, Present, and Future.* This is our second issue for this year, and our sixth year of providing two issues per year thanks to the interest of our readers and to the authors who work to produce such captivating articles. Also a big Thank You to our peer reviewers who respond quickly and with constructive comments to the authors, resulting in a higher quality publication. We always welcome volunteers to be peer reviewers; we appreciate your efforts and the burden is light.

Our peer-reviewers have had a selection of topics these past few months, so we gratefully acknowledge the authors who have taken the time to provide insightful and interesting stories to better trace our professional history through vignettes of the recent and distant past. We encourage our faculty and preceptor readers to enlist the aid of your

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Andrea Kjos
Chair
(andrea.kjos@drake.edu)

Karen Nagel-Edwards
Acting Past Chair
(KNagel@midwestern.edu)

Wesley Sparkmon
Chair-Elect
(wesleysparkmon@creighton.edu)

Eric Welch
Secretary of Knowledge Management
(Eric.Welch@uky.edu)

ANNOUNCEMENTS

Welcome from the Chair . . .
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collaboration. The Nominations Committee will draft slates for Chair-Elect and Secretary of Knowledge Management and oversee the inaugural History of Pharmacy Innovations in Teaching and Learning Award and Distinguished Educator Award, with calls for nominations expected in early 2026.

Overall, 2025–2026 will focus on strategic alignment, collaboration, and supporting scholarship and teaching. We encourage all members to stay connected through AACP Connect and to share ideas, questions, or suggestions as we move forward together.

Sincerely,

Andrea Kjos, SIG Chair

RECOGNIZE YOUR STUDENTS FOR THEIR ACTIVITIES RELATING TO THE HISTORY OF PHARMACY!

The American Institute of the History of Pharmacy offers certificates to students to recognize their achievements in the area of History of Pharmacy. Nominate deserving students at the link below. The certificates could be sent directly to the students or to the schools for presentation at an awards ceremony.

Link: #AIHP/ Student recognition certificate

Editor Message…
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students to add to our pages. A number of our articles have both teacher and student authors and they do a great job! Also, as many of our readers are teachers of pharmacy in so many disciplines, please take a moment as you organize your courses and lectures to incorporate some historical facts or context for drugs or diseases. One never knows where that spirit of inspiration will trip a memory or an area of interest!

Our issue this Fall focuses on some diverse topics. Three of the articles cover three relative recent drugs. Two of the drugs had immediate and dramatic impact when they were introduced, insulin and penicillin, and continue to significantly impact therapeutics in their respective fields. The third drug, thalidomide, also had a dramatic impact but for a more negative reason, but has made a positive therapeutic impact in more recent years. Our fourth article is on the history of black cohosh, a much older and traditional therapy.

Another article of significance is the book review for, *St. Hildegard's Garden: Recipes and Remedies for Healing Body and Soul*, that is as the title states. The author, Paul Ferris, bases his book on the writings of St. Hildegard of Bingen, a German Benedictine abbess who passed away in 1179 AD and is considered the founder of scientific natural history in Germany..

Please note that we welcome a short, newsy piece of trivia or a full article for peer review (1500-2000 words). Pictures are always good! To volunteer, contribute as author or peer reviewer or just have a question or suggestion, please feel free to contact either Megan Undeberg or Bernie Olin. We are always happy to hear from you.

—Bernie Olin, PharmD.,
Auburn University,
Harrison College of Pharmacy

Dispatch from the American Institute of the History of Pharmacy

Greetings from wintry Wisconsin! For those who aren't familiar with us, the American Institute of the History of Pharmacy (AIHP) is a nonprofit organization dedicated to preserving and promoting the history of pharmacy, which was founded and housed at the University of Wisconsin-Madison School of Pharmacy. We support scholarship, teaching, and public engagement through publications, programs, and archival resources. Our mission is to document the evolving field of pharmacy and ensure its stories are available for future generations.

We're delighted to announce that Bernie Olin has joined AIHP's Board of Directors as Treasurer! [https://aihp.org/meet-aihps-new-treasurer-dr-bernie-olin/] Bernie brings a wealth of experience and passion for pharmacy history, and we look forward to working with him for the next three years.

AIHP has partnered with the Consortium of the History of Science, Technology, and Medicine to create a Pharmacy History Working Group. This group meets monthly during the academic year to explore diverse topics in pharmacy history through engaging talks and discussion. Membership is free, and meetings are held on the third Wednesday of the month at 11:00 am Central via Zoom. To join, visit the CHSTM website, create an account, and request membership in the group. Learn more about the working group here. [https://aihp.org/upcoming-aihp-consortium-for-the-history-of-science-technology-and-medicine-pharmacy-history-working-group-meetings/]

Upcoming talks:

February 18:	Audrey Ke Zhao, UC Santa Cruz & CHSTM Research Fellow
March 18:	Ryan A. Kashanipour, University of Arizona
April 15:	TBA
May 20:	Mackenzie Cooley, Hamilton College (tentative)

AIHP has reinvigorated its internship program! Our interns have helped us expand our social media presence—including launching a TikTok account (@aihp1941)—and create new content for our *Dose of History* [https://aihp.org/dose-of-history-sister-pharmacists/] series. Do you have students interested in pharmacy history? Internships are no longer limited to Madison—we offer remote opportunities! Contact us at aihp@aihp.org for details.

AIHP is accepting applications for research fellowships open to both PhD and PharmD students. Fellows receive up to $3,500 to travel to Madison to conduct research in our archives. This is a great opportunity to engage deeply with primary sources and advance scholarship in pharmacy history. Full details about the fellowship can be found here. [https://aihp.org/aihp-accepting-applications-for-2026-aihp-phd-pharmd-research-fellowships/

We're hiring a Development Officer to lead fundraising initiatives and help advance AIHP's mission. This role is key to supporting programs, publications and outreach that preserve and promote pharmacy history. Read the full position description here. [https://aihp.org/aihp-development-officer-position-open/

The newest issue of *History of Pharmacy and Pharmaceuticals* is out! This latest issue showcases innovative, multidisciplinary research on pre-modern pharmacy drawing on diverse sources and languages to deepen our understanding of historical materials, techniques, and global pharmaceutical development. Become a member and get *HoPP* delivered to your door or access it online. A *HoPP* subscription is one of the many benefits of an AIHP membership. Support scholarship in the history of pharmacy, teaching the history of pharmacy, and preserving the history of pharmacy by purchasing a membership today. [https://aihp.org/support-mission/individual

Lucas Richert, PhD

Professor & George Urdang Chair in Pharmacy History, UW-Madison

Executive Director, American Institute of the History of Pharmacy

Transdisciplinary Center for Research on Psychoactive Substances

Editor at Social History of Alc & Drugs / History of Pharmacy & Pharmaceuticals

Kristen Huset, BA, MLIS

Program Manager, American Institute of the History of Pharmacy

The History of Black Cohosh: From Traditional Medicine to Modern Use

By Grayson Boatright, Callie Clements, PharmD Candidates 2027, Marilyn N. Bulloch, PharmD, BCPS, FCCM, SP, and Bernie R. Olin, PharmD

Auburn University

Harrison College of Pharmacy

Early History and Background

Black Cohosh (Actaea racemosa) is a perennial herb native to North America, particularly found in woodland areas of the eastern United States and Canada. It is referred to as black snakeroot, bugbane, bugwort, and squawroot.[3] The term "cohosh" originates from an Algonquian Indian word meaning "rough," which describes the plant's dark, tough, and twisted rhizomes that contain medicinal qualities. The plant reaches heights of 3 to 8 feet with a spread of about 2 feet. Its leaves are alternately arranged, three-pinnately compound, with sharply serrated edges and ending in a three-lobed leaflet (Figure 1).[4] Black Cohosh contains triterpene glycosides like actein, 23- epi-26-deoxyactein, and cimicifugoside; resin compounds such as cimicifugin; and aromatic acid derivatives, including caffeic acid, isoferulic acid, and fukinolic acid.[3]

Black Cohosh was first described in 1705 by botanist Leonard Plukenet, a prominent English botanist, in Phytographia, a major botanical work of the 1600s.[1] It was originally introduced as Christopheriana facie, Herba spicata, ex Provincia Floridana then the official botanical name was Actaea racemosa L., published in 1753 in Species Plantarum. After publication, the famous botanist Carl Linnaeus separated the genus Cimicifuga from Actaea. However, it was Thomas Nuttall who first referred to the plant as Cimicifuga racemosa in his 1818 book The Genera of North American Plants. The name Cimicifuga comes from Latin—"cimex" meaning "bedbug" and "fugare" meaning "to drive away." This name was chosen because some species in this group, like C. europaea, C. foetida, and C. elata, have a strong, unpleasant smell in their leaves, which was thought to help repel insects like bedbugs.[2] It has a long history of use in women's health, including menopausal symptoms, menstrual discomfort, and fertility. Today, Black Cohosh is commonly used for women's health and remains a subject of ongoing clinical research and regulatory discussions.[3]

Early Use of Black Cohosh

The initial medicinal use of Black Cohosh is commonly credited to Native Americans, who utilized it to treat a range of conditions, including female-specific issues like amenorrhea and menopause, as well as rheumatism, kidney problems, general fatigue, and pain during menstruation and childbirth.[5] As the traditional uses of Black Cohosh became more widely known, its medicinal potential caught the attention of early herbalists, physicians, and researchers in the United States.

Figure 1. Black Cohosh.

A perennial herb native to North America, black cohosh is shown here with its characteristic tall white flower spikes and dense green foliage, illustrating its distinctive botanical features. Looking more closely, you can see the characteristic serrated edges of Black Cohosh as mentioned above.

The first-time Black Cohosh was mentioned in medical writing was by Benjamin Smith Barton in 1798 in his work Collections for an Essay towards a Materia Medica of the United States, where he noted its ability to

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"Black Cohosh"

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tighten tissues (astringent effects).[2] In 1828, Constantine Samuel Rafinesque, a botanist and professor at Transylvania University in Lexington, Kentucky, expanded its known uses in his first volume of the medical flora; or Manual of the Medical Botany of the United States of North America. He described it as helpful for increasing urine flow (diuretic), promoting sweating (sudorific), easing pain (anodyne), repelling insects, stimulating menstrual flow (emmenagogue), and slightly strengthening the body (subtonic).[7] By 1832, John King, a well-known eclectic physician, was using a tincture of Black Cohosh (Macrotyn), to treat both short- and long- term rheumatism, as well as other inflammatory conditions. He also used it for health issues related to the lungs, nervous system (like chorea and nerve pain), and for disorders involving the female reproductive system.[2]

Figure 2, Lydia E. Pinkham Vegetable Compound

Lydia E. Pinkham Vegetable Compound included various herbs like black cohosh, known for easing menstrual and menopausal symptoms. The product reflects early use of plant-based remedies for female wellness.

Science History Institute. (2023). *Lydia E. Pinkham's Vegetable Compound for Menopause and Menstruation* [Photograph]. Science History Institute. https://digital.sciencehistory.org/works/wkzh43d

While many herbal products gained a popular following in early American history, Lydia Pinkham helped popularize the use of Black Cohosh in 1876 by utilizing it in one of her most famous products, Lydia E. Pinkham's Vegetable Compound (Figure 2). Mrs. Pinkham began making herbal concoctions in her home and distributed them to neighbors for years before formally marketing her product that could "cure any female complaint ."

The compound included Black Cohosh as a main ingredient along with true unicorn root (Aletris farinosa), and pleurisy root (Asclepias tuberosa). The Black Cohosh component in this compound was used to "treat symptoms of menopause, such as hot flashes, and to have sedative and anti-inflammatory properties that treated menstrual cramping."[8] Interestingly, this compound also had an alcohol content of 18%. According to Mrs. Pinkham, the alcohol was used solely as a "solvent and a preservative". This took on particular importance during the Temperance Movement when alcohol consumption faced strong criticism. This product was revolutionary during this time in history as it opened the discussion regarding female reproductive health and offered relief for women experiencing pain regarding menstrual and menopausal related issues. It also set the stage for other companies to start promoting women's health products in a more open way, which helped normalize conversations about menstrual and menopausal issues. However, no medical evidence was found to support Lydia Pinkham's claims regarding its effectiveness in treating menstrual or menopausal symptoms.[8,9] Today, the compound is still available for purchase as an over-the-counter supplement.

Black Cohosh in Modern Times

Black Cohosh is not FDA approved for any medical indication as it is an over-the-counter dietary supplement. It is promoted as helping with female-specific conditions, but it has not been indicated for any specific condition by any governing body in the United States. However, in 1989, Commission E, a German scientific advisory board that reviews and evaluates the safety and efficacy of supplements, approved extracts from the rootstock of Black Cohosh for treating "pre-menstrual discomfort, dysmenorrhea, and menopause-related symptoms."[10]

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The History of Insulin

By Mattie Smalley, Madison Piedra, Lucy Tocco and Bernie Olin

Harrison College of Pharmacy
Auburn University

Background

Diabetes mellitus is a chronic metabolic condition that impairs the body's capacity to respond to the hormone insulin, resulting in increased levels of glucose in the blood and urine. The classic symptoms include frequent urination, excessive thirst, and unexplained weight loss and these symptoms were recognized as far back as 1500 BCE in Egyptian medical writings.[1] Indian physicians also observed these indicators, and famously called the condition "honey urine" because of the sweet-smelling waste it produced.[2] As medical understanding progressed, diabetes was categorized into subtypes. Type 1 diabetes, which often begins in childhood or adolescence, is caused by an autoimmune process that destroys the pancreatic beta cells, which leads to a complete lack of insulin.[3] Conversely, Type 2 Diabetes, is a chronic condition typically diagnosed in adults, characterized by insulin resistance or relative insulin deficiency.[3] Before the discovery of insulin, treatment options for diabetes were severely limited. Physicians such as Frederick Allen (1879-1957) prescribed extremely low-calorie diets in an effort to reduce glycosuria and prolong life; however, these measures rarely extended survival beyond a few months.[2] In 1921, Frederick Banting and Charles Best successfully isolated insulin, marking a turning point in diabetes treatment.[2] For the first time, it became possible to address the underlying cause of disease. Their discovery transformed the prognosis of diabetes, turning a once-fatal illness into a condition that could be managed with proper therapy.

Early Concepts and Foundations in Diabetes Research: Antiquity to Early 20th Century

Early physicians and scientists gradually developed ideas about diabetes through observation and experimentation. The most concrete idea came from Aretaeus of Cappadocia who was likely active in 2nd Century AD and is known as one of the greatest physicians of the Greco-Roman era of antiquity after Hippocrates. Aretaeus, along with Galen noted that the disease caused excessive thirst, polyuria, emaciation, and eventual death.[2] Galen, a prominent Roman physician whose medical writings influenced Western medicine for centuries, contributed foundational terminology to the disease. Building on Galen's terminology, *diabetes diarrhea urinosa* ("diarrhea of the urine"), Aretaeus coined the term *diabetes* to reflect the excessive loss of fluid observed in affected patients. [2]

Centuries later, during the seventeenth century, Thomas Willis expanded upon these clinical observations by directly analyzing the urine of patients suffering from diabetes.[2] He observed that when urine was boiled down, a sugar-like residue was left behind. This finding marked an important shift toward linking diabetes with abnormalities in sugar metabolism rather than just fluid loss.

The anatomical basis for diabetes research advanced with the discovery of the pancreas by Johann Georg Wirsüng in 1642.[4] However, because the function of the organ was not yet understood, Wirsüng chose not to publish his findings and only engraved the drawing of the organ on a copper plate. Subsequent scientists continued to explore pancreatic anatomy, culminating in the work of Claude Bernard (1813-1878). Bernard demonstrated the exocrine function of the pancreas and, because the endocrine role of the organ had not yet been recognized, concluded that it functioned solely as an exocrine gland.[2,4] As a result, he initially proposed the lungs and later the liver as the central organs responsible for glucose regulation. Bernard ultimately theorized that diabetes resulted from a failure of glucose homeostasis and helped introduce the concept of gluconeogenesis, helping to pioneer the field of endocrinology and advance the scientific study of diabetes.[2,4]

A major turning point in diabetes research took place in 1889 when Oskar Minkowski and Joseph von Mering performed pancreatomies on dogs. Following the removal of the pancreas, they observed urinary glucose concentrations as high as twelve percent, leading them to hypothesize that the pancreas played a critical role in glucose homeostasis.[4] This discovery paved the way for multiple experiments by Marcel Eugene Emile Gley, who published findings describing a pancreatic extract that reduced urinary glucose when administered to

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The Historical Impact of Penicillin

By Lindsey Bricken, Carrington Kee, Kyle Trinidad, PharmD Candidates 2026

Bernie R. Olin, PharmD

Auburn University,
Harrison College of Pharmacy

Introduction: The Pre-Antibiotic Era

Introduction of penicillin to medicine transformed practice radically, marking the beginning of the antibiotic era. Treatable infections today were once life-threatening and frequently lethal. Pneumonia, septicemia, and tuberculosis mortality in the latter part of the 19th and early 20th centuries were high, and treatments were largely limited to antiseptics, modest wound management, and sulfonamide drugs, which caused harmful side effects and little universal efficacy.[1,2] A scratch or a postpartum infection were potentially deadly, and surgical procedures entailed significant risk. Also during this time, World War I was claiming millions of lives through untreated sepsis presenting as flesh wounds. This environment of severe uncontrolled infectious diseases emphasized the impact of penicillin's discovery.

The Accidental Discovery of Penicillin

September 1928, at St Mary's Hospital, London, bacteriologist Alexander Fleming returned from vacation to find mold growing on one of his culture dishes of *Staphylococcus aureus*. The mold, surprisingly, inhibited the bacterial growth around it.[4] His subsequent experiments suggested that this substance was non-toxic to tissues, which was a main quality that distinguished it from other current compounds. He documented the strong potential of this compound as a therapeutic substance. Fleming appropriately recorded this encounter, and, in 1929, he published his findings where Fleming described this "mold juice" killing and inhibiting Gram-positive bacteria, such as streptococci and staphylococci.[5,6]

Fleming named the active substance "penicillin" after the mold *Penicillium notatum*. However, he experienced challenges with purifying this substance. The compound was unstable, so it could not be easily prepared and it quickly degraded. With the purification methods of the time, penicillin remained a laboratory curiosity and not an exploitable medicine.[7] Fleming himself was skeptical of its therapeutic potential but did not possess the chemical expertise to bring its promise to fruition. Penicillin's potential lay latent for nearly a decade, unrecognized by most of the medical profession.[4,8]

Development into a Usable Drug: The Oxford Team

The practical transformation of penicillin from curiosity to medicine occurred a decade later at Oxford University. In 1938, Howard Florey, Ernst Chain, and Norman Heatley brought together an interdisciplinary team to study antibacterial compounds in nature. Ernst Chain had an interest in Fleming's paper, and the team set out to study penicillin's properties in earnest.[3]

Ernst Chain was crucial to this team as his expertise allowed him to more precisely demonstrate the properties of penicillin that killed bacteria; Norman Heatley's creativity in developing methods of extracting and purifying had been critical. Penicillin, utilizing surface culture methods, was effectively isolated in sufficient volumes by the Oxford men to be tested in animals and, later, in human experiments. In 1940, they published a landmark paper in *The Lancet* demonstrating the therapeutic efficacy of penicillin in mice infected with Streptococcus and Staphylococcus species.[3] For humans, however, about 3,000 times the amount of penicillin was needed to achieve therapeutic levels in comparison to mice, and so, Heatley designed a large container to grow more penicillin to better suit their needs.

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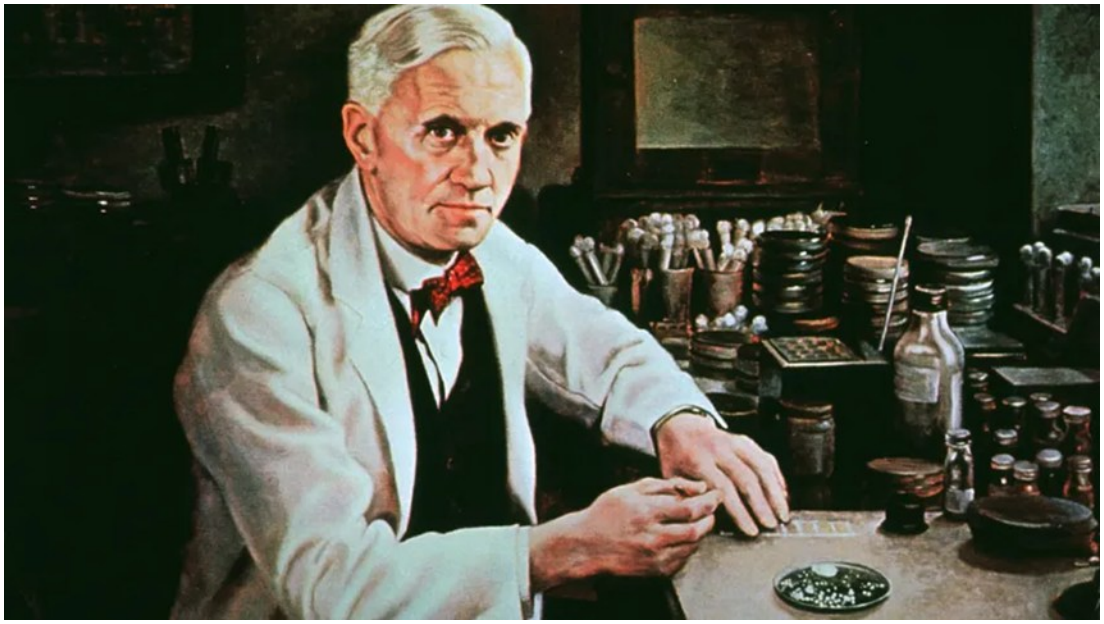

Figure 1: Rendered photo of Alexander Fleming in 1952. Image from: https://www.britannica.com/biography/Alexander-Fleming[9]

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The first human experiment occurred in February 1941, when a police officer named Albert Alexander, who suffered from an acute staphylococcal infection, was treated with penicillin. Initially, he made a dramatic improvement, but supplies soon ran out and he eventually died. The report presented hope for the life-saving capability of penicillin if it could be produced in large enough quantities.[7] Florey's wife, Dr. Ethel Florey, played a major role in helping to produce larger quantities by collecting urine from patients being treated with penicillin. Using penicillin extracted from urine, Howard Florey, Ethel Florey, Chain, and Heatley conducted a sequence of clinical trials in 1941 and 1942 in a total of 170 patients.[7] The Oxford team immediately recognized the potential impact this drug could provide to injured soldiers and wounded civilians during the ongoing World War II.

World War II and Mass Production

World War II created a sharp focus on the urgency to find successful treatments for infected wounds, pneumonia, and venereal disease in combatants. The positive results of the Oxford group prompted Howard Florey to attempt to get British pharmaceutical companies interested in producing penicillin. But because of several factors, mainly being the circumstances of the war, he failed. In July 1941, Florey, along with Heatley, traveled to the United States to convince their medical industry to take on the project of penicillin production. After several meetings and a good deal of determination from Florey, United States pharmaceutical companies agreed to begin the mission of mass-producing penicillin.[3] The production difficulties were immense. Standard surface culture methods were unproductive, making volumes as little as pinches. The eureka moment came after it was discovered that corn steep liquor, a by-product of corn processing, substantially boosted mold production. This, coupled with Pfizer's pioneering research in deep-tank fermentation, made it feasible to mass-produce penicillin.[8]

After the attack on Pearl Harbor, the US government sped up the process of manufacturing penicillin for their wounded soldiers. In the United States, the War Production Board was formed in 1943 to help regulate the mass production of penicillin, selecting 21 companies to undergo the production.[5] By the end of World War II, penicillin

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In a 2009 randomized, double-blind, placebo-controlled trial, Newton et al, compared three herbal regimens and hormone therapy for relief of vasomotor symptoms as compared to placebo in 351 women aged 44-55 with two or more vasomotor symptoms per day. This study further expanded the idea of whether Black Cohosh could truly provide relief for some women's vasomotor symptoms related to menopause. These symptoms could include hot flashes, night sweats, mood changes such as depression or irritability, sleep disturbances, headaches, muscle or joint pain, breast tenderness, nervousness, or palpitations. The participating women ranked their vasomotor symptoms with regards to frequency and severity. In addition, the Wiklund Vasomotor Symptom Subscale Score was also utilized to measure efficacy.

In this trial of 351 women, participants were assigned to one of five groups: black cohosh **160 mg/day** (80 women); a multibotanical herbal supplement containing black cohosh, alfalfa, dong quai, evening primrose oil, ginkgo biloba, licorice root, and valerian (76 women); the same multibotanical plus soy and dietary counseling (79 women); conjugated equine estrogen **0.625 mg/day** with or without medroxyprogesterone acetate **2.5 mg/day** depending on uterine status (32 women); or placebo (84 women). The results from this study showed that "Black Cohosh used in isolation, or in a multibotanical product, has little potential to play an important role in relief of vasomotor symptoms."[11] The difference in hot flash frequency was less than 1 symptom per day. One group (multibotanical plus soy) had worse symptom intensity at 12 months ($P = 0.016$). In contrast, hormone therapy significantly reduced hot flashes by an average of 4.06 per day (95% CI: −5.93 to −2.19; $P < 0.001$).

In conclusion, only 80 of the 351 participants received Black Cohosh alone. The remaining participants were divided into other herbal combinations, hormone therapy, or placebo. Black Cohosh showed little to no improvement in frequency or severity of hot flashes compared with placebo. The hormone therapy group who received conjugated equine estrogen and medroxyprogesterone acetate showed improvement with 4 fewer hot flashes per day. This 2006 trial provided updated evidence regarding the efficacy of Black Cohosh, which led to a further, more inclusive, meta-analysis in 2023.

More recently, a 2023 meta-analysis utilizing 22 studies, Sadahiro et al, reviewed and analyzed the use of Black Cohosh alone versus Black Cohosh combined with other related active ingredients in 2,310 women. The outcomes focused on changes in menopausal symptoms after treatment with Black Cohosh in menopausal women. Contrary to the outcomes in Newton et al, Sadhiro et al., showed that Black Cohosh significantly improved menopausal symptoms. The researcher found moderate, significant reductions in overall menopausal symptoms (Hedges'g = 0.575, $P<0.001$), as well as in hot flash frequency and severity (Hedges' $g = 0.315$, $P = 0.003$). Somatic symptoms, such as muscle aches and sleep issues also showed moderate improvement (Hedges' $g = 0.418$, $P = 0.001$). However, the analysis did not find any significant findings for improvement of anxiety or depression symptoms. This recent meta-analysis provides insight into the effectiveness of Black Cohosh today as compared to earlier studies that took place at the turn of the 21st century. Building on the evidence supporting its effectiveness, it's also important to consider the potential risks associated with Black Cohosh use, particularly reports of liver-related toxicities that have raised safety concerns in recent years.[12]

Safety, Liver Toxicity, and Inactive Ingredients

While many people use Black Cohosh, there have been some reports of liver damage linked to its use. In a 2021 case, a 44-year-old woman experienced liver inflammation and jaundice shortly after starting Black Cohosh.[13] Another case described a 50-year-old woman who developed severe itching and yellowing of the skin after taking the supplement for two months, which improved once she stopped.[14] While these are important toxicities to note, there is not a definitive link between Black Cohosh and liver damage (including hepatitis, liver failure, elevated liver enzymes, and other liver dysfunction). The exact cause is unclear, but the injury appears to be idiosyncratic and not related to dosage. Some patients showed autoimmune-like features, and symptoms often improved after stopping the supplement.

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"Penicillin" . . .
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was made widely available to Allied armies and became referred to as the "war's miracle drug." As a result of mass production, one advantage seen was the drop in the price of penicillin from $20 per dose in 1943 (equivalent to $373.50 today) to $0.55 per dose in 1946 (equivalent to $9.54 today), thus allowing more people to be able to receive the drug with its increased access.[8] Mortality from infection of wounds and pneumonia dropped significantly, and penicillin saved thousands of soldiers' lives and limbs on the battlefield.[1,3] A sufficient supply of penicillin was even maintained for the Allied forces during the invasion of D-Day.

The success of penicillin during the war and with mass production sealed the role of collaboration between academic scientists, governments, and industry in medical advances.

Switzerland Discovery and Patents

Meanwhile, the Axis Powers, primarily the Germans, were also striving to produce penicillin. They requested a sample of the mold *P. notatum* from a company in the Netherlands called Centraalbureau voor Schimmelcultures (CBS, who Fleming had sent a sample to in the 1930s). The company could not refuse, but knowingly sent them the sample that did not grow the penicillin substance. Efforts to produce penicillin in the Netherlands, then went underground at a company called the Nederladsche Gist-en Spiritusfabriek (NG & SF). With the help of a Jewish part-time advisor, Andries Querido, they extracted a substance from the mold *P. baculatum*, which they named Bacitrol as a code word to avoid the German's discovery. They began the production of Bacitrol, but were not certain it was the same compound as penicillin, until later when they tested it against some penicillin from England. It indeed was the same compound, and so they began marketing their penicillin in January 1946.[11]

This began the controversial problem of a patent for penicillin. Ernst Chain believed it was crucial to obtain a patent, while Florey and the others saw it as unethical. At the time Great Britain's view was that a process could be patented, and so Merck and Andrew Jackson Moyer filed for patents on the process of producing penicillin with no opposition. Because NG & SF had their own process and development of penicillin using their own mold culture, they were not involved in any patent clash. The marketing of NG & SF eventually even increased penicillin demand and decreased prices of penicillin, making it more available to patients in need.[11]

Post-War–Nobel Prize and "Golden Era" of antibiotics

By the end of World War II in 1945, American pharmaceutical companies produced about 650 billion units per month of penicillin.[4] Later that year, Fleming, Florey, and Chain were jointly awarded the Nobel Prize in Physiology or Medicine.[8] In Fleming's Nobel lecture, he warned about the dangers of misusing penicillin and creating resistance to the drug, which began sooner than Fleming may have anticipated.

The first case of resistance was seen in 1947, and so began the global search for more antibiotics, which is now referred to as the "golden era" of antibiotics. With the help of advanced X-ray crystallography in 1945, Dr. Dorothy Crowfoot Hodgkin was able to confirm the molecular

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Figure 2: Photo from National World War II museum; advertisement for penicillin in Life Magazine August 14, 1944 issue.[10]

"Black Cohosh"

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It is believed the liver injury may result from an immune reaction to certain compounds or contaminants in the product, rather than from direct liver toxicity.[19] Thus each bottle can vary depending on active and inactive ingredients. Most of the implicated products contained the Chinese Acetea species rather than Black Cohosh. Finally, inactive ingredients such as fillers, dyes, preservatives, and binders within the Black Cohosh supplements are also proposed to be the cause of liver dysfunction, rather than the Black Cohosh itself. Currently, there are no Black Cohosh supplements that are United States Pharmacopeia (USP) certified. This is important to acknowledge as USP certification verifies a supplement for correct identity of the ingredient, purity, potency, and quality of manufacturing. Without this certification, each black cohosh supplement product varies widely leading to an increased likelihood of mislabeling, contamination, or adulteration, all of which may contribute to reported cases of liver toxicity attributed to Black Cohosh.

Other important adverse effects that have been noted include gastrointestinal symptoms and rashes, both are acknowledged to be transient and resolve upon discontinuation of Black Cohosh.[16] It has been found that patients taking Black Cohosh have not been seen to develop a tolerance nor do these patients suffer from withdrawal symptoms.[17] Black Cohosh has no known addictive or psychoactive effects, and there are no reports of misuse when used appropriately. Black Cohosh is available in multiple dosage forms, including dried rhizome or root, liquid extracts, and tinctures. Common daily doses range from 40–200 mg of the dried root, ethanolic extracts standardized to the equivalent of 40 mg of dried rhizome/root, and 0.4–2 mL of tincture.[15] The dose varies per form, so it is always important to check the supplement label. A safe daily dose is 20–80 mg, but concentrations vary by product.[17,18]

Conclusion

Black Cohosh has an evolving history, from being used by Native Americans for various health problems to becoming a well-known natural remedy for women going through menopausal symptoms. Over the years, it gained attention from early herbalists and made its way into popular products such as Lydia Pinkham's formula. Even though it's not approved by the FDA as a drug, Black Cohosh is still widely used today for hot flashes and other menopause-related symptoms. Recent research shows it may help some women, but there are also safety concerns, especially when it comes to liver dysfunction. Black Cohosh doesn't carry a risk of resistance or abuse. Its long history and continued use today show how traditional remedies can still be valuable but should be used carefully and studied more to fully understand their effects.

—Grayson Boatright and Callie Clements,
Auburn University Harrison College of Pharmacy,
PharmD Candidate Class of 2027
Marilyn N. Bulloch, PharmD, BCPA, FCCM, SP
Auburn University Harrison College of Pharmacy and
Bernie R. Olin, PharmD,
Auburn University Harrison College of Pharmacy

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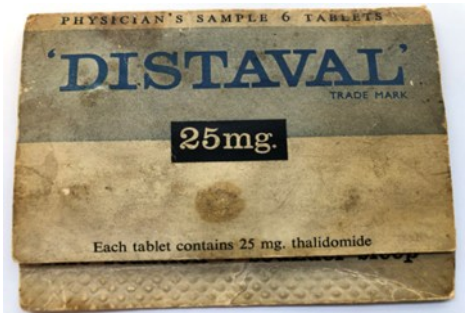
The Thalidomide Story: From Horror to Hope

By Logan Davis, Zinza Hepburn, and Whitt Krehling
Bernie R. Olin, PharmD

Auburn University
Harrison College of Pharmacy

Discovery of Thalidomide

Thalidomide, otherwise known as Contergan, is a compound that was originally developed in the 1950s by the West German pharmaceutic company Chemie Grünenthal GmbH. Dr. Wilham Kunz and Dr. Herbert Keller created thalidomide through a three-step process that included N-phthaloyl-L-glutamine and carbonyl diimidazole. The first synthesized product of thalidomide in 1954 was a product of their research into glutamic acid. Thalidomide is the racemic derivative of glutamic acid, with the (S)-isomer contributing to its effects on inhibiting TNF-alpha and the (R)-isomer contributing to its sedative effects. The medication is metabolized quickly into many more active metabolites, then excreted primarily in the urine.[2]



Once discovered, the company patented the drug in the same year and began testing it for its sedative effects. Initial testing in animals indicated that the drug caused low toxicity with no increase in toxic effects at higher doses. After animal studies, thalidomide was then tested in human clinical trials for its sedative properties in healthy subjects that were known to have anxiety or insomnia. These tests resulted in few side effects, giving the belief that the drug was safe for humans. In both the animal and human trials, thalidomide was not directly tested for the potential to cause birth defects (teratogenicity) or the effect it would have on embryos or fetuses that were exposed to the drug. The lack of testing within pregnant patients led to what we now know as the thalidomide disaster.[1,3]

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structure of penicillin, which would help lead to the development of other antibiotics and substances like vitamin B12.[5,8] With the advent of penicillin resistance, methicillin was formed in 1959 to combat microbes resistant to penicillin. Eventually in 1961, reports in the United Kingdom revealed cases of *Staphylococcus aureus* that were resistant to methicillin, leading to the term methicillin-resistant *Staphylococcus aureus*, otherwise known as MRSA.[12] With resistance to penicillin forming, the need for other antibiotics grew.

Between the years 1940 to 1960, one-half of the antibiotics used today were discovered, including tetracyclines, macrolides, and vancomycin.[8] With its early formation, several variations of penicillin were also made throughout this time, like cephalosporins and anti-staphylococcus penicillins.[8] Overall, the foundation of penicillin led to the formation of many other antibiotics, signifying its vast influence in the field of medicine.

Conclusion

Penicillin's accidental discovery changed the outcomes for thousands of patients. At a time when treatment was urgently needed to treat wounded soldiers in World War II, the efforts of Alexander Fleming, the Oxford Team, along with collaboration with American pharmaceutical companies allowed the development and extensive production of penicillin. The introduction of penicillin signaled the beginning of the "golden era" of antibiotics, altering the management of infectious disease and dramatically decreasing mortality from previously fatal diseases. Today, penicillin and its derivatives are still essential components of modern medicine and serve as the foundation for antimicrobial therapy. They continue to shape public health on a global scale; however, the overuse of antibiotics has played a part in the rise of antimicrobial resistance, which is now recognized as one of the most urgent global health challenges, emphasizing the need for stewardship and ongoing research for new therapeutic strategies.[15]

Penicillin resistance is still an issue in today's healthcare community as bacteria are continuing to evolve to evade these drugs. This is leading to more difficult-to-treat infections and greater healthcare costs. According to the World Health Organization (WHO), it is estimated that bacterial antimicrobial resistance was responsible in 2019 for 1.27 million deaths globally. By 2050, this resistance could result in $1 trillion additional healthcare costs.[15] The history of penicillin should provide the public with an important lesson of the importance of continued scientific research, international collaboration, and the need to focus on antimicrobial stewardship for the remaining efficacious antibiotics in use today.

Lindsey Bricken,
Carrington Kee, and
Kyle Trinidad
PharmD Candidates 2026 and

Bernie R. Olin, PharmD
Auburn University
Harrison College of Pharmacy

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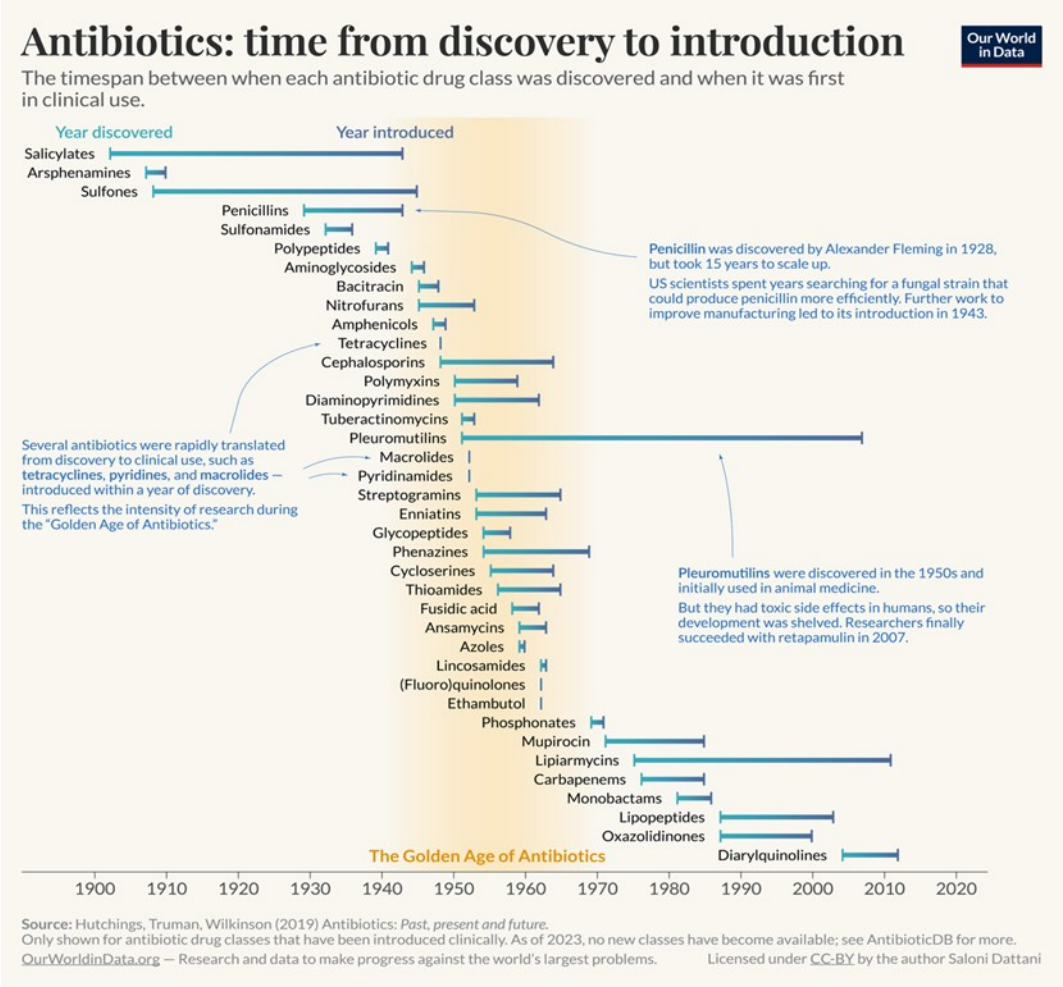

Figure 3: Timeline of the discovery of various antibiotics made by Saloni Dattani[13] with data derived from Hutchings et al. (2019)[14]

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to animals.[4] Although this work represented the first demonstration of an antidiabetic hormone, Gley was unable to fully characterize the substance or explain its mechanism of action. It was not until the 1920s that this hormonal treatment was more clearly defined, ultimately leading to the discovery of insulin.

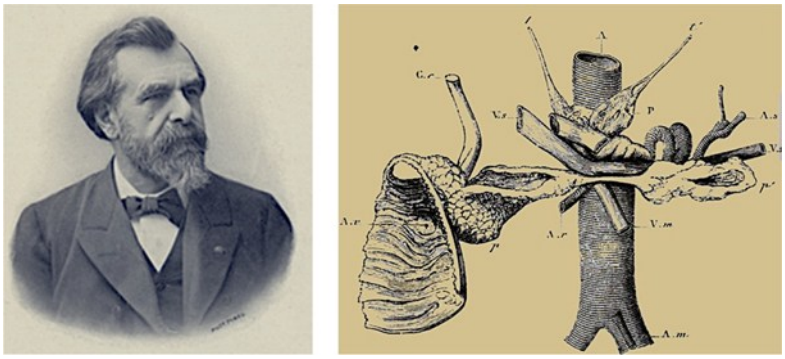

Figure 1. Minkowski with his diagram of the pancreas.

Discovery of Diabetes Treatment

Frederick Banting was a Canadian surgeon who began his research at the University of Toronto in the laboratory of John MacLeod, a lecturer and head of physiology research.[2] Banting drew inspiration from earlier work by Minkowski, von Mering, and Gley, all of whom had demonstrated a connection between the pancreas and glucose regulation. Banting collaborated with Charles Best, a then medical student, to investigate this relationship further. They crushed small pieces of animal pancreas and injected it into animals that lacked a pancreas, and observed decreases in blood sugar similar to those of the findings of Gley.[2] To improve the consistency and safety of the extract, James Collip joined the team in 1921 and successfully purified the substance into something they were able to replicate.[2] This purified extract, later named insulin—a term coined in 1916 by Edward Albert Sharpey-Schafer from the Latin *insula,* meaning "island," in reference to the pancreatic islets—was subsequently tested in humans.[2] The first human trial was on 14-year-old Leonard Thompson. Prior to these trials, the only recommendation for human treatment of diabetes was "mangez le moins possible" or "eat as little as possible." Most patients were severely malnourished, emaciated, and did not live very long. At first, the insulin was insufficiently purified and Thompson became very sick.[2] They reformulated and purified it, and Thompson lived another 13 years before succumbing to pneumonia. Subsequent trials demonstrated consistent therapeutic success, firmly establishing insulin as an effective treatment for diabetes.[2, 6]

In 1923, the Nobel Prize for Physiology or Medicine was awarded to Frederick Banting and John MacLeod for the discovery of insulin.[7] This award is marked by much controversy, as Banting believed that he should share the prize with Best. In response, Banting shared half of his cash award, while MacLeod also shared his award with Collip. That same year, the group collaborated with Eli Lilly Pharmaceutical Company and made the first commercially available insulin, Iletin, marking the beginning of widespread insulin therapy for diabetes.[2, 7]

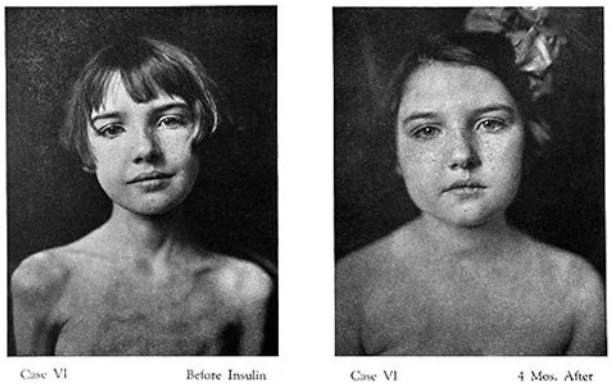

Figure 2. Pictured is a young girl before, and 4 months after insulin.

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Evolution of Insulin Production

In the 1920s, the production of insulin required large quantities of cow and pig pancreas, which were waste products of the meatpacking industry.[8] Pork and beef-based insulin was able to bind to insulin receptors on cells and signal glucose uptake from the bloodstream, effectively lowering blood glucose levels. One of the problems with this method, however, was that both the pork and beef-based products differed slightly in amino acid sequencing, signaling to the immune system that it was a "foreign" product. This led to antibody production and immune reactions in some patients, and over time even decreased the effectiveness of the products.[8]

Another barrier that manufacturers encountered was the vast quantity of animal products required to actually produce the insulin. In the era of pork insulin, nearly two tons of pig pancreas were needed to produce only eight ounces of insulin.[8] The unsustainability of this process was evident, and scientists recognized that continued innovation as needed to improve the accessibility and scalability of insulin therapy.[9]

By the 1970s, advances in the insulin purification process led to purer insulin that was not as susceptible to resistance.[10] However, the supply and cost of insulin still depended on the availability of the animal glands, leaving many patients without reliable access. This unstable supply chain prompted significant innovation in 1978, when researchers at Genentech, in collaboration with City of Hope, developed a method to produce biosynthetic human insulin using recombinant DNA (rDNA) technology.[10] Scientists took two protein chains, A and B, that make up the human insulin gene and introduced them to a common bacteria strain, reprogramming its genetic instructions so that insulin could be manufactured on a much larger scale.[8] This breakthrough offered a way to meet growing global demand, as access to insulin remained limited for many, especially in low-income countries where availability and affordability were major barriers.[9]

Eli Lilly & Co. signed an agreement with Genentech to use the rDNA technology method to make human insulin commercially available, and in October 1982, after only 5 months of review, the FDA approved Humulin. It became the first approved medical product on the market to utilize the rDNA technology, and was the first biosynthetic human insulin product.[10]

Advances in Insulin Formulations and Delivery

Insulin formulations have evolved significantly to provide varying durations of action, allowing for more precise blood glucose management. Short-acting insulins, often taken before meals, work quickly to cover carbohydrate intake and manage post-meal glucose spikes, typically lasting for a few hours.[11] Intermediate-acting insulins have a slower onset and a longer duration, providing basal insulin coverage for a portion of the day.[11] Finally, long-acting insulins are designed to provide a steady, peakless supply of insulin throughout the entire day (up to 24 hours or more), mimicking the body's natural basal insulin production and helping to control glucose levels between meals and overnight.[11] The choice of insulin type depends on individual needs, lifestyle, and the specific goals of diabetes management.

Beyond traditional vial and syringe methods, a variety of advanced insulin delivery systems have been developed to enhance convenience, accuracy, and patient adherence. Insulin pens are pre-filled or reusable devices that offer a discreet and easy way to administer insulin, often preferred for their portability and ease of use compared to vials. Insulin pumps are small, computerized devices that deliver continuous, precise doses of insulin throughout the day and night through a catheter placed under the skin, offering highly flexible and personalized insulin delivery that can adapt to changing needs. Additionally, inhaled insulin provides a needle-free option for some individuals, rapidly delivering insulin into the bloodstream via the lungs to manage mealtime glucose.[11]

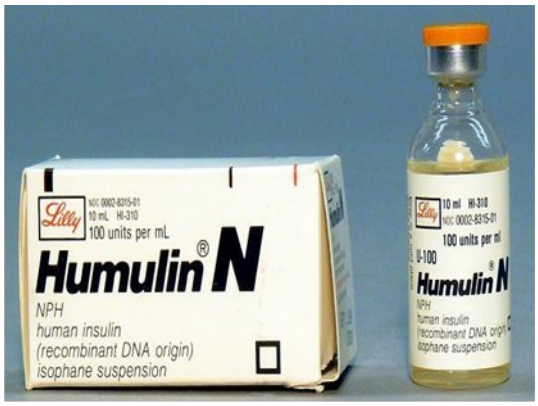

Figure 3. Eli Lilly's Commercial NPH Product

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Original Use of Thalidomide

Thalidomide was originally put on the market intended to be used as a sedative or sleep aid but was soon to be found used for a variety of conditions such as colds, influenza, nausea, and morning sickness during pregnancy. By the mid-1950s, fourteen pharmaceutical companies were marketing thalidomide in 46 countries under several different trade names (Distaval, Tensival, Valgraine, Asmaval). The drug was advertised as safe in pregnant women and nursing mothers despite a lack of testing in these patient populations.[3]

Teratogenicity Discovered

In the late 1950s researchers began to see babies being born with congenital defects and malformations, specifically shortened limbs. While some abnormalities were expected, they saw a high rate and investigations were initiated to determine the cause. Thalidomide advocates believed that it could not have been due to the drug since there had been births that had no abnormalities at all, but birth defects in babies continued to increase from 1958 to 1961. In June of 1961, William McBride, an obstetrician in Sydney, Australia, became well known for his research and drawing attention to the teratogenic effects of thalidomide. McBride had seen an unusual increase in children he was delivering at Crown Street Women's Hospital. He then decided to investigate and found the common denominator of the birth defects in the infants was that their mothers had taken thalidomide for either morning sickness or as a sleep aid during the pregnancy. This led to McBride publishing a letter to The *Lancet* describing what he had observed. He wanted to know if any other physicians had seen the same problem regarding the teratogenic effects.[4] The publishing of the letter occurred around the time when pediatrician Widukind Lenz of Germany also saw malformations in the children he had been treating. This

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Continuous Glucose Monitoring (CGM) represents a technological advancement that has enhanced the delivery and optimization of insulin therapy. CGM systems consist of a small sensor worn under the skin that measures interstitial fluid glucose levels throughout the day and night, transmitting data wirelessly to a receiver, smartphone, or insulin pump.[11] When integrated with insulin pump systems, CGM data allow for more precise insulin dosing by identifying glucose trends and fluctuations that would otherwise go undetected. This integration has facilitated the development of sensor-augmented pumps and automated insulin delivery systems, enabling insulin administration to more closely mimic physiologic insulin secretion. In this way, CGM technology represents a critical evolution in the history of insulin therapy, shifting treatment from reactive glucose correction toward proactive and automated insulin management.[11]

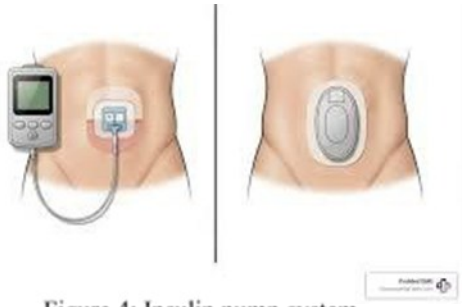

Figure 4: Insulin pump system

Global Impact and Accessibility Issues

A 2009 study examined survival outcomes in patients who began insulin treatment at the time of diabetes diagnosis, focusing on individuals under the age of 40 who died between 1946 and 2005.[9] A total of 845 patients from the "I. Pavel" Bucharest Diabetes Centre were included and divided into two groups based on age at diagnosis: Group A included those diagnosed before age 18, and Group B included those diagnosed between ages 18 and 39.[9] Over the six decades studied, both groups experienced increases in survival with diabetes, with an average gain of 19.3 years in Group A and 15.9 years in Group B. There was no change in age at onset, but the increased survival led to a significant rise in age at death. The study also observed a significant reduction in infection-related deaths in both groups. However, increases in coronary heart disease and stroke-related deaths were observed only in the older group. These findings suggest that improvements in diabetes care have contributed to extended life expectancy in insulin-treated patients. Despite the clear benefits of early insulin access, availability remains limited in many parts of the world, which continues to threaten the outcomes of patients who rely on this life-saving therapy.[9] Additionally, a 2021 report from the World Health Organization (WHO) titled "Keeping the 100-year-old promise – making insulin access universal" further details the alarming global situation of insulin access.[12] This report highlights that despite insulin's 100-year history and its critical role in turning a deadly disease into a manageable one for millions, particularly the nine million with type 1 diabetes and over 60 million with type 2 diabetes, access remains severely limited for many.[12] The WHO identifies high prices, the shift from affordable human insulin to more expensive insulin analogs, market control by just three major pharmaceutical companies, and weak health systems as the primary contributors for these barriers. The report tragically notes that nearly half of those who need insulin for type 2 diabetes do not receive it, and while most people with type 2 diabetes live in lower-income countries, these regions account for less than 40% of global insulin sales revenue.[12] This imbalance reveals a market that largely favors wealthier populations, neglecting the substantial diabetes burden in underserved regions.

Future of Insulin Therapy

The future of insulin therapy promises a revolutionary shift towards "smart insulins," which are designed to respond to blood glucose levels in real-time, potentially simplifying diabetes management.[13] Scientists have developed these innovative insulin formulations, often described as a "holy grail" because they aim to mimic the body's natural response to changing blood sugar, activating when needed and becoming less active when glucose levels fall. This could lead to a reduction in the frequency of insulin administration, with some experts suggesting that patients may only need to take this form of insulin once weekly. Unlike current synthetic insulins that merely stabilize blood glucose only after administration and cannot prevent subsequent spikes or dangerous lows, smart insulins are intended to maintain stable glucose levels automatically. This development is especially significant for the millions living with type 1 diabetes, who currently face the burden of injecting insulin multiple times daily, often experiencing constant fluctuations

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Book Review
St. Hildegard's Garden: Recipes and Remedies for Healing Body and Soul

Reviewed By Tracey L. Mersfelder

Ferris State University

St. Hildegard's Garden is a compelling book that appeals to a wide range of readers, especially those interested in the history of pharmacy, the healing power of plants, and/or a patron saint associated with the profession. The book is structured into three main parts, preceded by a preface. The preface sets the stage on how the author approached the contents of the book with maintaining the information written by St. Hildegard and incorporating modern knowledge.

Part 1 explores St. Hildegard's life. Emphasizing her deep Catholic faith, her prolific writings, and her enduring legacy. St. Hildegard of Bingen, a German Benedictine abbess passed away in 1179, and her work remained largely forgotten until the 1970's. A movement began out of Europe to revitalize her work that ultimately led to her recognition as a Doctor of the Church in 2012 and she is considered the founder of scientific natural history in Germany.

Part 2 is the heart of the book, focusing on the plants St. Hildegard recommended for healing. Each plant is presented with her original descriptions, supplemented by clarifications from the author. Each entry includes a dedicated page of text followed by a full color illustration. With 60 plants featured, this section functions more as a reference than a narrative. It concludes with helpful gardening tips, covering everything from garden design and planting to harvesting and preserving.

Part 3 delves into remedies and recipes. It begins with an overview of 15 common ingredients, noting whether St. Hildigard recommended their use or avoidance. The remedies section includes instructions for preparing 13 medicinal wines, 12 teas and drinks, 1 powder, and 16 topical applications. Where St. Hildegard's original texts lacked specifics, the author thoughtfully provides quantities and preparation guidance. The final portion of this section offers 16 kitchen recipes, each introduced with a quote from St. Hildigard and accompanied by instructions. Like Part 2, this section serves more as a reference or cookbook than a continuous narrative.

In summary, *St. Hildegard's Garden* offers readers a concise yet rich glimpse into the life and wisdom of a remarkable woman whose insights into healing and spirituality remain relevant today and worth reading. A word of warning, the author advises that anyone interested in herbal remedies should possess a solid understanding of botany or consult their herbalist or pharmacist.

Tracey L. Mersfelder ,PharmD,
Professor of Pharmacy Practice
Ferris State University

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led him to believe that thalidomide was a possible cause. After reading Dr. McBride's letter, he felt certain that his assumptions were correct. Lenz contacted Chemie Grünenthal GmbH where it took a total of eleven days to discuss the finding of the birth defects and the connection with thalidomide before it was withdrawn from the market. After the drug had been withdrawn from the German market, countries such as Belgium, Brazil, Canada, Italy, and Japan continued to sell thalidomide for several months. By 1973, it was estimated that 2,400 cases of malformations could be credited to the use of thalidomide.[5] While thalidomide was being used worldwide and available over-the-counter (OTC), the United States Food and Drug Administration (FDA) never formally approved thalidomide for marketing and distribution. However, thalidomide was studied in the U.S. and had been distributed to at least 20,000 patients, including pregnant women under the guise of a trial. The participants were given minimal or no knowledge on the experimental drug that they received. As the awareness of thalidomide's teratogenic effects rose, clinical trials were ceased. Shedding light on the need for stricter regulations to approve drugs.[3]

Dr. Frances Oldham Kelsey

Dr. Frances Kelsey was a pharmacologist at the University of Chicago in the early-mid 1900s. In 1954, she began teaching pharmacology at the University of South Dakota, where she practiced general medicine. In 1960, she received an offer to work for the FDA as one of their few medical officers. This job required her to review New Drug Applications, a situation that led to the initial thalidomide application making it to her desk. Due to a lack of safety data, Dr. Kelsey refused the application. The company pressured her multiple times to no avail. What may have seemed like a small act of perseverance and ethics, ended up saving countless lives from the tragedy of the thalidomide disaster. Dr. Kelsey would eventually take on a role as the head of the investigational drugs branch which would lead her to head the division of scientific investigations from the late 1960s into the 1990s.[6]

Kefauver-Harris Amendment of 1962

The Estes Kefauver- Oren Harris Amendment of 1962 was influenced by the thalidomide tragedies. This amendment mandated that drug manufacturers must demonstrate that a drug is both safe and effective before the drug can be approved and put on the market – where the original requirement was that pharmaceutical companies only had to provide proof that the drug was safe. With this mandate came the clinical trial process and the requirement of informed consent from participating patients. This change to the Food Drug and Cosmetic Act significantly strengthened U.S. drug regulation. Oversight of prescription drug advertising was transferred from the Federal Trade Commission to the FDA, and advertisements were required to disclose side effects and other important drug information. The law formalized Good Manufacturing Practices and mandated the reporting of adverse events. Notably, the amendment was applied retroactively, prompting the FDA to review drugs approved between 1938 and 1962 to ensure they were both safe and effective.[7]

Global Impact, Legal Battles, and Compensation Efforts

Within the five years of thalidomide being on the market, it is estimated that over 10,000 infants were affected by the drug worldwide. Many died within months of being born, not making it to their first birthday and those who did survive had to live with the tragic abnormalities and disabilities it caused. The Thalidomide Society was formed in 1962, consisting of the parents who had children affected by thalidomide. The Society helped support one another, raise money for those

Figure 4 – Young children affected by thalidomide pictured taking swimming therapy in 1962. https://betterbeginnings.org/who-we-are/history/

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struggling financially, and began the battle of seeking compensation and recognition from the pharmaceutical companies.[8] Chemie Grünenthal went to trial in May of 1968 to determine if the company was at fault for the thalidomide consequences. The criminal trial lasted two and a half years but was discontinued with no verdict. A civil settlement then took place in which Chemie Grünenthal agreed to paying 100 million German Marks ($59,340,545.39 in United States Dollar today) to the Federal Thalidomide Foundation, which continues to provide financial support to those affected by thalidomide in several countries.[9] This support is distributed as one-time payments for urgent issues, monthly payments to supplement income, and grants for costs not typically covered by the normal payments.

Thalidomide Back on the Market

Thalidomide underwent extensive testing after it was removed from the market and was found to have immunomodulatory and anti-angiogenic properties. After rigorous testing the drug was FDA approved in 1998, specifically for the treatment of erythema nodosum leprosum (ENL). In 2006, the FDA also approved its use for treatment of multiple myeloma with steroids. Thalidomide, new brand name Thalomid, is currently indicated for the following: AIDS-related aphthous stomatitis, erythema nodosum leprosum (acute cutaneous and maintenance), graft vs host disease (chronic and refractory), multiple myeloma (previously treated, maintenance therapy following hematopoietic cell transplant, relapse or refractory), systemic light chain amyloidosis, and Waldenström macroglobulinemia. Although approved for several different conditions, thalidomide has a U.S. boxed warning of embryo-fetal toxicity, and venous thromboembolism.[12] The use of the drug is heavily restricted and managed through the Thalidomide Risk Evaluation and Mitigation Strategy (REMS) program which prevents risk of embryo-fetal exposure to the drug and informs patients, prescribers, and pharmacist of serious or unsafe conditions of thalidomide. This program requires patients to sign a patient-physician agreement form, consent to monthly pregnancy tests, use of two forms of birth control while taking the drug, mandatory patient counseling by a pharmacist, a four-week supply allowed with no refills and must be picked up within seven days of the written prescription.[11]

The Future of Thalidomide

Though thalidomide had its downfall with a history of teratogenicity, there is still ongoing research to further its use. It is currently being used for multiple myeloma, conditions caused by leprosy, and other inflammatory conditions previously mentioned. Thalidomide's existence has contributed to the development of other new immunomodulatory drugs like lenalidomide (Revlimid) and pomalidomide (Pomalyst). Ongoing research on thalidomide and its analogs is exploring their potential in combination with innovative treatments such as antibody–drug conjugates and bispecific antibodies. To maximize safety and effectiveness, scientists are working to better understand the drug's mechanisms of action and develop more targeted therapies. Strengthening pharmacovigilance systems for reporting and analyzing adverse drug reactions remains essential to prevent future tragedies. In parallel, research is addressing the long-term social and health consequences faced by thalidomide survivors, including co-morbidities and the lifelong impact of disability.[10]

Conclusion

Thalidomide, synthesized in 1954 by West Germany's Chemie Grünenthal, was initially marketed as a sedative and widely used across 46 countries under multiple trade names. It was also found effective for nausea and morning sickness in pregnancy. Inadequate testing for teratogenicity allowed its use in pregnant women, ultimately resulting in thousands of infants born with severe malformations, particularly limb defects. Key physicians, Dr. William McBride in Australia and Dr. Widukind Lenz in Germany, identified the link between maternal thalidomide exposure and birth defects, prompting withdrawal in some regions but not worldwide. The tragedy directly influenced the 1962 Kefauver–Harris Amendment, which mandated that drugs demonstrate both safety and efficacy, informed consent in clinical trials, strengthened regulatory oversight, and formalized good manufacturing practices. Globally, over 10,000 infants were affected, many of whom faced lifelong disabilities, emphasizing the human cost of inadequate drug testing. Survivor advocacy through the Thalidomide Society secured critical support and compensation, highlighting the importance of patient-centered accountability. Following extensive evaluation, thalidomide was reintroduced under strict FDA REMS guidelines for conditions such as erythema nodosum leprosum and multiple myeloma, reflecting its potential when used safely. The thalidomide legacy underscores the necessity of rigorous preclinical and clinical

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evaluation, ethical responsibility in drug development, and robust pharmacovigilance, serving as a lasting reminder that medical innovation must always prioritize patient safety to prevent history from repeating itself.

—Logan Davis, Zinza Hepburn, and Whitt Krehling
Harrison College of Pharmacy
Auburn University
PharmD Candidates Class of 2026

Bernie Olin, PharmD
Associate Clinical Professor,
Director of Drug Information Center
Harrison College of Pharmacy
Auburn University

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between high and low blood sugar that can lead to serious complications such as eye damage and heart disease. This breakthrough aims to ease the relentless daily management for those with diabetes, moving closer to a therapy that mimics the precise control of a healthy pancreas.[13]

Moving beyond manual management, the future of insulin therapy also includes Artificial Pancreas Systems, which represent a significant leap forward by integrating insulin pumps and continuous glucose monitoring (CGM) systems to automate insulin delivery.[13] These "hybrid closed-loop systems" continually monitor a person's blood glucose levels and automatically adjust the amount of insulin administered through a pump, effectively taking over some of the pancreas's functions. This groundbreaking technology was recently announced for national rollout by the National Health Service (NHS) in England, following encouraging trial results, for tens of thousands of children and adults with type 1 diabetes. This decision followed the results of a 2023 Cambridge University-led trial, which showed that patients using the artificial pancreas spent about three additional hours per day within their target blood glucose range compared to standard insulin pump users.[14] The system also significantly reduced both hypoglycemia and hyperglycemia events, contributing to improved overall quality of life.[14]

In addition to technological advances, surgical approaches such as pancreas transplantation are considered for select patients, particularly those with severe type 1 diabetes who are not achieving adequate glucose control with conventional therapies. According to the Mayo Clinic, pancreas transplants are most commonly performed alongside kidney transplants in patients with end-stage renal disease, though they may also be performed alone in specific cases.[15] While the risks are higher due to the need for lifelong immunosuppressive therapy, the potential benefits include restored natural insulin production and freedom from insulin injections. Despite the promise of these emerging therapies, access remains limited, presenting an ongoing barrier to equitable diabetes care.

Conclusion

There have been many interpretations, experiments, and theories that have contributed to a deeper understanding of diabetes and insulin in the modern world. From early observations of

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disease symptoms to the discovery of insulin and the continued refinement of insulin therapies, continuing progress has dramatically changed the course of diabetes care. New innovations continue to emerge and revolutionize the diabetes landscape. This progress has opened the door to improved glucose control, less invasive treatment options, fewer side effects and diabetes-related hospitalizations, and greater quality of life for patients living with this disease. As research and technology continue to advance, the future of insulin therapy continues to hold promise for not only better disease management but also for more accessible care for patients worldwide.

—Mattie Smalley, Madison Piedra, and Lucy Tocco
Harrison College of Pharmacy
Auburn University
PharmD Candidates Class of 2026

Bernie R. Olin, PharmD
Associate Clinical Professor,
Director of Drug Information Center
Harrison College of Pharmacy
Auburn University

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