ORRIN G. HATCH
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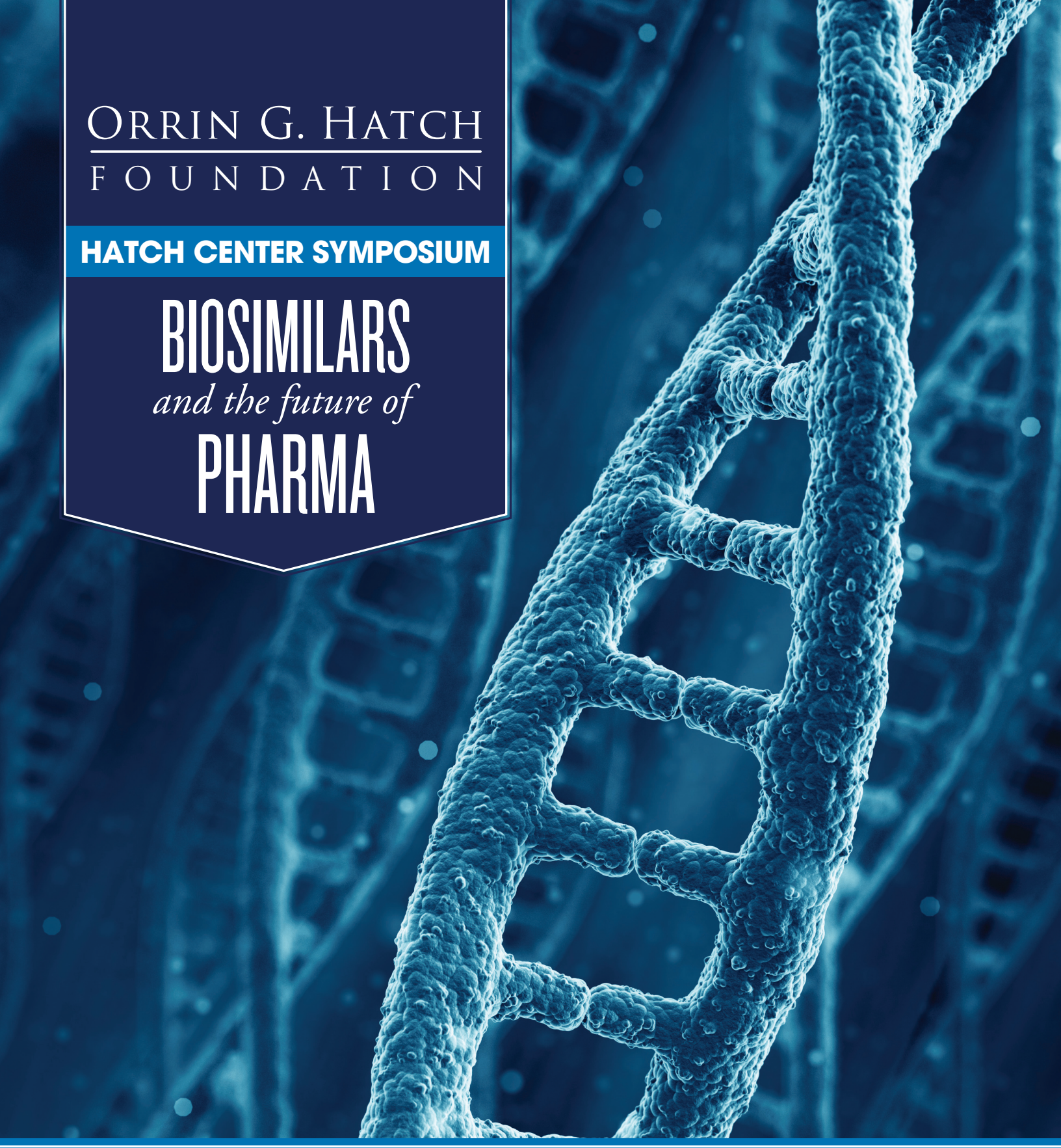
HATCH CENTER SYMPOSIUM

BIOSIMILARS
and the future of
PHARMA



SYMPOSIUM REPORT

March 2020

Introduction

As the nation grapples with the effects of COVID-19, debates on the adequacy of our health care delivery system have taken center stage. This has yielded an intense focus on America's ballooning health care costs, skyrocketing drug prices, and disparities in treatment availability for certain geographic populations, socio-economic classes, races, and diseases. In part, the discussion has turned to biologic products—a broad category of drugs composed of proteins, sugars, or nucleic acids, often derived from natural sources. While these products offer irreplaceable solutions to gaps in effective treatment modalities, they also impose significant costs on our healthcare system: by themselves, biologic products make up 40 percent of our nation's drug costs but only 2 percent of all prescriptions,[1] and from 2010–2015, they alone accounted for a 70 percent increase in drug spending.[2] Thus, crafting sensible solutions to both foster innovative biologics and curb skyrocketing drug prices is paramount to shaping sustainable health policy going forward.

Currently, the biologics market consists of more expensive brand-name products with few lower-cost alternatives. Protecting originator—or "pioneer"—biologics is fundamental to promoting the development of innovative new treatments. Yet in recent years, we have also witnessed an increase in "biosimilars," the lower-cost alternative to brand-name biologics. These follow-on products hold the promise of dramatically lowering health care costs, saving the economy billions of dollars, and, most importantly, providing patients greater access to lifesaving treatment. Harnessing the benefits of and promoting biosimilars thus holds the key to saving the economy and health care system over $100 billion in the next five years.[3]

That said, policymakers must understand the delicate balance between protecting pharmaceutical innovation and robustly clearing unnecessary obstacles impeding the growth of biosimilars. For the generic drug market, Senator Orrin G. Hatch and other influential lawmakers balanced these objectives through the Hatch-Waxman Act. Similarly, Senator Hatch and others strove to strike this same balance for the biologic and biosimilar markets through the Biologics Price Competition and Innovation Act of 2009 (BPCIA). The BPCIA continues to be foundational to the strength of the growing biotechnology industry today.

Despite our progress in enacting this hard-fought legislation, however, many have cited the barriers to

biosimilars that have developed over time, limiting our realization of BPCIA's cost-saving benefits. Recognizing this, the Hatch Center—the policy arm of the Orrin G. Hatch Foundation—brought together patient care experts, legislators, and policymakers in its March 2020 health care symposium to underscore the benefit of biosimilars and explore ways to overcome these barriers. This report summarizes that symposium and extends that dialogue, providing concrete policy recommendations to increase biosimilar ubiquity and use while maintaining the necessary balance between promoting innovation and lower-cost alternatives.

Following a brief primer on biosimilars, their history in the United States, and a summary of the Hatch Center's March symposium, this report discusses the core obstacles facing biosimilar access and uptake, and recommends sensible solutions that can be adopted moving forward. Following the example of Orrin Hatch in his longstanding commitment to civility and bipartisan solutions, we will make great strides towards a sustainable market marked by innovation, cost-savings, and lifesaving access to these indispensable treatments.

Alex M. Azar II

Secretary, US Department of Health and Human Services

Alex Azar was sworn in as President Trump's Secretary of Health and Human Services in January 2018. The Department of Health and Human Services is the largest cabinet department in the federal government by spending, with a budget of $1.2 trillion in 2018. It is charged with enhancing and protecting the health and well-being of all Americans. The Department encompasses not just health care programs such as Medicare and Medicaid, but also scientific institutions such as CDC, NIH, and FDA; human-services programs at the Administration for Children and Families; and preparedness and response work to protect Americans from natural disasters, infectious disease, and other threats.

Secretary Azar has spent his career working in senior health care leadership roles in both the public and private sectors. His current tenure at HHS is a second tour of duty at the Department. He served as HHS's General Counsel from 2001 to 2005, and then as Deputy Secretary—the Department's number-two official and chief operating officer. During his time as Deputy Secretary, Azar played key roles in international affairs and global health diplomacy, implementation of the new Medicare prescription drug program, public health emergency preparedness and response efforts, and food and drug regulation. He also led the Department through several successful management and operational transformations.

Secretary Azar earned a BA in Government and Economics from Dartmouth College and a JD from Yale Law School.

Matt Sandgren

Executive Director, Orrin G. Hatch Foundation

Matt Sandgren serves as the executive director of the Orrin G. Hatch Foundation, a nonprofit organization focused on promoting commonsense solutions to the nation's most pressing problems. Previously, Sandgren directed the legislative, communications, and political activities as Senator Orrin G. Hatch's chief of staff during his final and most effective years as a lawmaker.

A Capitol Hill Veteran with more than 15 years of experience, Sandgren also served as senior counsel on the Senate Judiciary Committee. Beyond intellectual property and technology policy issues, Sandgren's legislative portfolio spanned a significant portion of the Judiciary Committee's jurisdiction, including biotechnology, pharmaceutical (Hatch-Waxman), cybersecurity, immigration, internet governance, and privacy issues. He likewise served as Senator Hatch's staff director for the Senate Republican High-Tech Task Force and as lead counsel for the International Creativity and Theft Prevention Caucus.

Sandgren earned a BA from Brigham Young University, a JD from The University of Tulsa, and an LLM from The George Washington University. He is a member of the Utah, District of Columbia, and US Supreme Court bars.

Biosimilars: A Primer

Biological products are a broad category of medical treatments derived and made from living organisms found in humans, animals, yeast, or microorganisms.[4] These products can be composed of anything from sugars, proteins, or nucleic acids to living entities like cells and tissues.[5] Biologics include not only products like insulin and vaccines, but also therapeutic proteins like filgrastim and pelfigrastim or monoclonal antibodies like infliximab and adalimumab.[6] In contrast to small-molecule drugs (such as cholesterol or blood-pressure medications), biological products are much larger molecules;[7] structurally more complex;[8] and often require special processing, handling, and administration procedures to ensure purity and efficacy.[9] Accordingly, biologics are far more difficult to create, produce, distribute, and (key to this discussion) *replicate* than their small-molecule cousins. Replication is especially difficult as the efficacy of a biologic integrally depends on the manufacturing process—a process that is often protected by layers of patents.[10]

Patented versions of these products are called "biologics" or (for purposes of making similar copies) "reference products." Once a biologic's patents expire, other drugs manufacturers can create and market lower-cost follow-on products, or "biosimilars." In purpose, biosimilars are akin to small-molecule generic drugs, designed to provide greater access to treatment at lower costs. Unlike generic drugs, however, biosimilars cannot identically replicate a reference biologic because of that product's inherent complexity and proprietary production process.[11] In other words, generics are *identical* to an innovator drug while biosimilars can only *approximate* the reference product—hence the name, bio*similar*.[12] Though not identical per se, biosimilars must be "highly similar" to a reference product with "no clinically meaningful differences." The current laws and regulations also contemplate so-called bio-identical or "interchangeable" products (though such products do not yet exist in the market today).[13] This distinction is critical as biosimilar prescriptions must be filled as specifically written by a provider, whereas a pharmacist may fill a prescription for an "interchangeable" biosimilar product without provider intervention. This is similar to many current state laws, under which pharmacists can on their own substitute brand-name prescription drugs with interchangeable generic drug products.[14]

To approve a biosimilar, a manufacturer must demonstrate that the follow-on product is highly similar in purity, structure, and functionality to a reference biologic.[15] And though there may be minor technical differences between a biosimilar and a reference product,[16] FDA approval and the monitoring processes are designed to ensure there is no clinical difference in safety or effectiveness between products when used for patient treatment.[17] After demonstrating biosimilarity, a manufacturer can then rely on the reference biologic's far lengthier (and costlier) approval process to receive an FDA license. To be sure, because of the complexity of these products, biosimilar approval is still a

more rigorous approval process than the application process for generics drugs (which itself is already rigorous). But the cost of launching a biosimilar (around $100 to $200 million) is still far lower than launching a pioneer biologic (over $2 billion).[18]

The benefits of these products are many. Biologic products have provided many of the recent breakthroughs in medical therapies for serious and life-threatening illnesses like cancer, rheumatoid arthritis, psoriasis, Crohn's disease, diabetes, HIV/AIDs, multiple sclerosis, and other rare diseases.[19] Moreover, these products are often the *only* treatment for these diseases.[20] Biosimilars, in particular, have the potential to provide the same medical benefits, but at a lower cost. Patented biologics are incredibly expensive, costing on average $10,000-$30,000 per year, with the most expensive products exceeding $500,000 per year.[21] For patients, lower-cost biosimilars will provide greater access to these lifesaving medications.[22] And for the country, biosimilars will dramatically decrease our nation's soaring health care costs, saving as much as $150 billion from 2017 to 2026.[23] With biologic spending representing 40 percent of all prescription drug spending,[24] this reduction will save the overall economy billions of dollars as well.

Legislative Efforts & the Biologics Price Competition and Innovation Act

In 1984, Senator Hatch joined with Representative Henry Waxman to forge the historic bipartisan compromise that revolutionized small-molecule drug markets: the Drug Price Competition and Patent Term Restoration Act (known more commonly as "the Hatch-Waxman Act").[25] This Act led to a dramatic increase in the production and use of generic drugs, with massive

savings to the US economy and American consumers.[26] Two decades later, Senator Hatch recognized the potential benefits of biosimilars, which were not covered by Hatch-Waxman, and set out to provide American patients with the benefits of a similarly thriving biosimilar market.

Long before the Senator's involvement, biologics regulation began with the Biologics Act of 1902, an initial law which regulated the nascent vaccines and biological products market through manufacturer-licensure and product-labeling requirements.[27] By the early 21st century with biosimilar availability beginning to grow in Europe[28] and US drug prices soaring, the possibility of creating an approval pathway for lower-cost biosimilars in the US became more compelling.[29] In 2006, the FDA approved its first biosimilar through an abbreviated pathway known as "505(b)(2)" after a US district court ruled that it was required to do so. In comments on the ruling, FDA clarified it "d[id] not establish a pathway" for approval of other biosimilars—Congress would need to legislate such a pathway.[30]

In 2007, Senator Hatch approached members on both sides of the aisle and urged formation of a working

Andy Schmeltz

Global President and General Manager, Pfizer Oncology

Andy Schmeltz is the Global President and General Manager of Pfizer Oncology, responsible for an industry-leading, innovative portfolio of cancer medicines. As a 16-year Pfizer veteran, Andy has held multiple leadership positions throughout the organization. Prior to assuming his current role, Andy was the head of Pfizer's Patient and Health Impact Division, accountable for ensuring that patients around the world gain affordable, timely access to medicines. Andy also held the role of Chief Commercial Officer for Pfizer Internal Medicine, with accountability for the franchise's $9 billion global portfolio of cardiovascular, metabolic, neuroscience, and pain medicines.

Prior to Pfizer, Andy spent seven years at Abbott Laboratories in several senior positions. He holds a BA in Economics from Columbia University and an MBA from the University of Chicago's Booth School of Business.

group to craft a legislative pathway for lower-cost biologic alternatives.[31] Initially, the Hatch-Waxman Act served as the model, but because of how different the development and manufacture of small-molecule drugs and biologics are, the group concluded it had to start from scratch.[32]

After many months of work, with abundant consultation of legal, pharmaceutical, and government experts here and abroad, the Senators reached agreement on legislation. The framework of the bill honored the balance inherent in the Hatch-Waxman Act. Because the proposed legislation provided both intellectual property protections for innovators and created a new pathway for the FDA to approve biosimilars without full review, the bill garnered support from innovators, patient groups, and others who were initially opposed to the legislative effort. The bill was criticized by some for providing too much marketing exclusivity to innovators, and by others for making it too easy for biosimilars to be approved potentially raising safety concerns. But in true Hatch fashion, all weakening amendments were rejected by healthy margins, and the bill was unanimously approved in committee through bipartisan compromise.[33] With the integral leadership of key House members and a very hard-fought battle in the Energy and Commerce Committee centering largely on the length of marketing exclusivity provisions, the Biologics Price Competition and Innovation Act was signed into law in 2010.[34] Several years later, the FDA issued its first guidance documents for approving biosimilar products, and it was not until last year that the FDA issued guidance for approving interchangeable products.[35]

At its core, BPCIA created an abbreviated process for the FDA to approve biosimilars while contemplating future approval of interchangeable products, much like the Hatch-Waxman Act did for generic small molecule drugs.[36] Though the FDA does not play a direct role in drug pricing, under both laws it does play an important role in "minimizing the time and cost to develop these products and in promoting effective competition."[37] Moreover, the Act established approval standards, a 12-year exclusivity period for innovator biologics, and a preemptory method of resolving patent disputes.[38] To be licensed as a biosimilar, an application need only demonstrate the statutory requirements for biosimilarity or interchangeability rather than go through the full biologics license application process.[39]

After BPCIA was enacted, Congress passed legislation to implement the requirement to fund the new program through assessment and collection of user fees: the Biosimilar User Fee Act of 2012.[40] It has also enacted provisions in the 21st Century Cures Act providing the FDA with more funding and modernized mechanisms to accelerate the approval process for new drugs like biologics.[41] Among other notable developments, the FDA has recently promulgated guidance on what constitutes an "interchangeable" product,[42] the President recently signed an executive order granting Medicare Part B and D the "most-favored-nation price" for small molecule and biological drugs.[43]

A Need for Reform

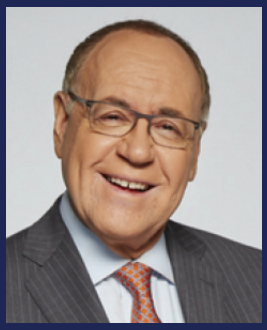
Despite substantial efforts to spur greater use of biosimilars, the US has not seen the expected increase in biosimilar approvals with their concomitant benefits. As a case study, contrast this with the years following the enactment of the 1984 Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman). Only a decade after enactment, the Hatch-Waxman Act is credited with over $1 trillion in savings to the health care system. By 2017 alone, consumers saved more than an estimated $265 billion. In fact, largely due to Hatch-Waxman, today over 90 percent of all prescriptions in the United States are filled with generic drugs.[44]

In contrast, consider the biosimilar market following BPCIA's enactment in 2010: a decade later, biosimilars still struggle to gain predominant market share.[45] The first biosimilar was not approved until 2015,[46] and by 2017, five biosimilars were approved with only three of those also being marketed.[47] To date, there are only 28 FDA-approved biosimilars, with no approved interchangeable products.[48] Compare these numbers with Europe: since the first approval in 2006, European regulators have approved over 50 biosimilars.[49]

With over 200 products currently in development,[50] the number of approved biosimilars should dramatically increase over the next decade. But without first addressing the barriers that have impeded past growth, we may not realize the full economic and treatment benefits that these lifesaving products can offer. The Biosimilars Council, a division of the Association for Accessible Medicines focused on promoting biosimilars, estimates that an increase in biosimilar availability could provide more than 1.2 million US patients with access to these lifesaving products,[51] with up to $150 billion to the US economy in savings over the course of the next decade.[52] This shows how critical it is to identify and craft bipartisan policy solutions in order to overcome barriers to realize these benefits.

Symposium Summary

In light of the tremendous, unrealized promise that biosimilars hold for American healthcare, the Hatch Center focused its March symposium on the current state of biosimilars and the future of this market. Experts, policymakers, patient providers, and legislators provided keynote addresses and panel discussions, offering key insights into the state of the biosimilars market and possible solutions going forward. This section provides a brief summary of the participants' remarks.



Marc Siegel, MD

Professor of Medicine at NYU School of Medicine, Medical Director of Doctor Radio on SiriusXM, Fox News Medical Correspondent

Marc Siegel, MD is a clinical professor of medicine, medical director of Doctor Radio at NYU Langone Health and a medical correspondent for Fox News, as well as a practicing internist. He is a graduate of Brown University, Suny Buffalo School of Medicine, and completed his residency at NYU Medical Center/Bellevue Hospital in internal medicine. He grew up in New York City. Dr. Siegel has published several books on influenza, infectious outbreaks and the fear epidemic. He is the author of the 2011 book "The Inner Pulse: Unlocking the Secret Code of Sickness and Health," and is completing a novel about a bioengineered virus. He was consulted by the US Senate Finance Committee regarding the anthrax mailings in 2002.

Dr. Siegel is a member of the board of contributors at *USA Today,* a columnist at *The Hill,* and a regular contributor to *The Wall Street Journal* and *National Review.*

Juliana Reed of the Biosimilars Forum and Dr. Marc Siegel of the NYU School of Medicine provided the first keynote addresses. Reed highlighted the savings benefits that come from increasing biosimilar market share. Even with the market "operating at full force" for the last 10 years, she said, biosimilar approval and usage has been less than ideal. With the potential to save tens of billions of dollars over the next decade, it is imperative, Reed urged, that biosimilar access and use improve to stem the country's burgeoning health care costs.

Following Reed, Dr. Siegel identified some of the many barriers contributing to the biosimilars access problem, including anticompetitive practices, excessive patent litigation, high entry and production costs, foreign dependence for supply chain inputs, and lack of provider and patient education. Only by overcoming these barriers will the country maximize the benefits of biosimilars, he said.

The first panel—which included Anna Hyde of the Arthritis Foundation, Annette Guarisco Fildes of the ERISA Industry Committee (ERIC), Dr. Sameer Awsare of the Kaiser Permanente Medical Group, and Pam Traxel of the American Cancer Society-Cancer Action Network (ASC-CAN)—focused on patients and providers.

Hyde acknowledged the importance of increased production of and access to these products, but she underscored the accompanying need to understand both patient and prescriber perspectives. Without understanding these perspectives and developing best practices for conversations between patients and providers, she said, biases and fear of change will inhibit the use of already approved products.

Guarisco Fildes recognized the role that policymakers, manufacturers, patients, and providers play, also

emphasizing the role of employers in improving the rate of biosimilar usage. Biologics are often the highest cost driver of employer health care plans, she noted, but increasing access to biosimilars will help companies provide their employees with the best care at sustainable costs.

Dr. Awsare shared his experience at Kaiser Permanente and the success that organization has had. He related that Kaiser has seen an 82 to 98 percent uptake in biosimilar use (compared to 2 percent for the rest of the country) by increasing focus on educating physicians and patients, reversing perverse financial incentives for prescribers, and publishing its own data on biosimilar effectiveness.

Traxel next highlighted how successful biologics have been in cancer treatment and thus how integral biosimilars are for those patients. Unfortunately, she noted, the costs of biologics often force patients to choose between potentially lifesaving treatment and preserving family assets; but with biosimilars, more patients will be able to receive treatment without jeopardizing their families' financial footing.

Juliana Reed

VP, Global Corporate Affairs Lead, I&I and Biosimilars, Pfizer; President, The Biosimilars Forum

Juliana Reed is the Vice President of Global Corporate Affairs for the Pfizer Immunology, Inflammation and Biosimilars business. Ms. Reed has been engaged in global biosimilar policy for over 15 years through her current position as well as her previous work as Vice President of Global Government Affairs for Hospira, Inc. Ms. Reed has direct pre- and post-approval market experience in multiple countries across at least nine biosimilars on the market today. She is an internationally recognized expert on biosimilars.

In addition to her corporate positions, Ms. Reed has previously served on the board of the Generic Drug Association (GPhA/AAM) in the US, the board of Medicines for Europe, and was a co-founder of the US Biosimilars Forum where she is currently serving as the Forum's President for the past 6 years.

Anna Hyde

VICE PRESIDENT, ADVOCACY AND ACCESS, ARTHRITIS FOUNDATION

Anna Hyde is the Vice President of Advocacy and Access at the Arthritis Foundation, where she oversees both the federal and state legislative programs, in addition to grassroots engagement. Her focus is to raise the visibility of arthritis as a public health priority, build support for federal and state legislation that ensures access to affordable, high-quality health care, and enhance patient engagement in the policymaking process. Anna previously served as Senior Director of Advocacy and Access, managing the federal affairs portfolio and overseeing the state advocacy team.

Prior to joining the Arthritis Foundation in 2014, Anna worked as Senior Manager for Federal Affairs at the American Congress of Obstetricians and Gynecologists. She began her health policy career as a Congressional Fellow for Energy and Commerce Committee members. Anna received a BA in History from Southern Methodist University and an MA in Political Science from American University.

Andy Schmeltz of Pfizer Oncology gave the third keynote address, recognizing the role of incentives in promoting biosimlars. Even if we overcame the barriers impeding biosimilar creation, approval, and marketing, Schmeltz cautioned that the country would not realize the billions of dollars in savings without also incentivizing patients and providers to use these drugs. Accordingly, he recommended a two-pronged cost-savings model that would realign these incentives: First, he said this model would reduce or eliminate out-of-pocket costs for many patients, yielding approximately $3 billion in savings to patients and $5 billion to taxpayers. Second, Schmeltz said, the plan would pilot a shared-savings model, allowing providers a portion of these savings when prescribing biosimilars. He added that realigning these incentives will be particularly critical to overcoming entrenched behaviors and the unintended consequences of existing policies. By financially incentivizing physicians to prescribe biosimilars and by reducing out-of-pocket costs for patients, Schmeltz said he is confident that biosimilar use will increase.

The second panel—which included Representative Michael Burgess of the House of Representatives, Alex Brill of the American Enterprise Institute, Wayne Winegarden of the Pacific Research Institute, and Brett Baker of the US Senate Committee on Finance—focused on the health care system.

Representative Burgess, former chair of the Energy and Commerce Health Subcommittee, is confident biosimilars will be yet another story of American success much like the development of penicillin during World War II or the rise of generics. To achieve this success, Burgess cautioned, however, Congress must pass legislation to further democratize the biologic products market while still protecting innovation. He said that legislation to improve pricing structures and overcome information asymmetry, misinformation, and current deceptive practices is critical to this endeavor.

Brill acknowledged that biologic products must be approached differently because of how these products differ economically and technically from small-molecule drugs. That said, backward-looking metrics (e.g., the number of biosimilars approved by the FDA and the number of biosimilars actually launched into the market) along with forward-looking metrics (e.g., the number of products in the FDA's biosimilar development program) are important to overcoming both entry and usage barriers, he noted.

Winegarden shared two solutions he thought would be most effective. First, he said, there should be some combination of shared savings, star-ratings for

insurers (similar to the quality measures used in the MedicareAdvantage program) and higher reimbursements for providers to better incentivize biosimilar use. Second, Winegarden recommended reforming the exclusivity period and "patent dance" while maintaining protection for innovators to dramatically decrease the barriers facing biosimilar creation and production.

Finally, Baker agreed that incentives are key, but also emphasized that focusing on what is best for patients is necessary as well. Doctors want to do what is best for their patients, and by helping them understand how equally effective biosimilars are, doctors will naturally prescribe these products more frequently.

Secretary of Health and Human Services Alex Azar II concluded the symposium. His keynote address lauded the success the country has already had with biosimilars. He highlighted recent agency efforts making biosimilars more accessible and desirable for patients to use. These include: the FDA's Biosimilar Action Plan, finalized rules defining key terms in the BPCIA, an updated and online Purple Book (listing FDA-approved biologics and biosimilars), and the FDA's joint efforts with the FTC to combat anticompetitive effects. Azar said the Administration supports bipartisan legislation to reduce drug prices and that the goal of reducing costs through pharmacy-level interchangeability supported by data and science is within our reach. He noted success in the generic drug market took time, education, and cultural acceptance. He expressed that same hope and confidence for biosimilars. Soon, the Secretary hopes the US will join our global peers in Europe, fully capturing the treatment and savings benefits of these products.

Barriers & Solutions

A common theme which ran through the symposium was that the abundant, potential benefits of biosimilars for American patients were being held back through their slow uptake. Many of the participants identified specific barriers impeding that success. In general, these obstacles can be divided into two broad categories: patients' inability to access biosimilars ("availability barriers"); and barriers to patients actually using the products ("uptake barriers"). As Ms. Hyde and several other symposium participants noted, simply increasing biosimilars availability is not enough to provide patients with the benefits of these lower-cost medications. Instead, comprehensive policymaking must also address uptake barriers, or obstacles keeping patients, prescribers, insurers, and employers from actually using the biosimilars that are available. Accordingly, the next two subparts address these two types of barriers along with solutions to overcome them.

Biosimilar Availability

This section focuses on regulatory and market forces impeding biosimilar availability. Despite BPCIA providing a regulatory pathway for the creation, production, and sale of biosimilars, relatively few biosimilars are on the market. By removing these barriers, the number of created, approved, and marketed biosimilars should increase, providing greater access to these products.

The Patent Dance

Perhaps the greatest barrier to biosimilar availability is the uncertainty stemming from issues involving

Annette Guarisco Fildes
President and CEO, The ERISA Industry Committee

Annette Guarisco Fildes is President and CEO of The ERISA Industry Committee (ERIC), leading the association's public policy advocacy mission. Annette is a strategic public policy and political counselor with over 30 years of experience involving complex legislative and regulatory matters in the US and abroad. She began her legal career at the Internal Revenue Service Office of Chief Counsel and later practiced law at the Dewey Ballantine law firm. She also served previously as counsel to Senate Majority Leaders Bob Dole and Trent Lott. In the corporate world, she was a member of the senior executive team at General Motors, where she advised the GM Board of Directors on global public policy. She was also an executive with Honeywell International government affairs, and Executive Vice President of Public Affairs at the Retail Industry Leaders Association.

Annette has a BBA in Finance and a JD from Hofstra University, as well as an LLM in Taxation from Georgetown University Law Center.

Sameer V. Awsare, MD, FACP

Associate Executive Director, The Permanente Medical Group

Dr. Sameer Awsare is an Associate Executive Director for The Permanente Medical Group (TPMG), where he oversees adult and family medicine, mental health, pharmacy services, risk-adjusted coding, revenue cycle, pain services, and outside medical services for the organization. He also leads the work for TPMG's opioid initiative.

Dr. Awsare joined TMPG in 1993. In addition to his clinical responsibilities, he served as a Member of the TPMG Board of Directors from 1997 to 2014 and served as its Secretary from 2000 to 2006. He also served as Chair of the Board's Governance Committee and the Vice Chair of the Board from 2006 to 2014. He is currently the Secretary and Chair of the Governance Committee of the Mid-Atlantic Permanente Medical Group Board.

Dr. Awsare received his BS in Biology and his MD from the University of California, Irvine. He has served on the voluntary clinical faculty at the Stanford University School of Medicine.
Dr. Awsare is a fellow of the American College of Physicians.

biologic patents and the approval process. The BPCIA created the so-called "patent dance," a two-phased back and forth between a biosimilar applicant and a biologic product sponsor. Under the BPCIA and after the FDA accepts a biosimilar applicant's abbreviated biologics license application (aBLA), the applicant must provide the reference biologic sponsor with full access to its application and manufacturing process.[53] The biologic sponsor then reviews the information and returns a list of all unexpired patents that may present infringement issues.[54] In response, the applicant then addresses each listed patent with any unenforceability, noninfringement, or invalidity contentions.[55] This back and forth continues for several months, resulting in a final list of patents that the innovator will assert in federal court.[56] The second phase begins 180 days prior to launching an approved biosimilar during which time an innovator may seek an injunction for any patents listed during the first phase but not asserted, or the applicant may seek declaratory judgment in response to any of the remaining patents.[57]

While drafters of the BPCIA contemplated the patent dance being mandatory, the US Supreme Court's 2017 ruling in *Amgen v. Sandoz*[58] and the Federal Circuit's 2017 decision in *Amgen v. Hospira*[59] held it to be voluntary. This made the process even more uncertain. Now, applicants cannot be forced to engage in this patent dance or to continue it once they have started. Instead, they have two options: (1) join the dance to achieve some litigation certainty or (2) eschew the dance to avoid drawbacks. Often aBLA applicants choose not to dance to avoid exposing confidential processes to a competitor—describing in detail their patent contentions before an innovator provides its own, or incurring the costs of expensive pre-litigation exchanges.[60] In short, the intent of this process—designed to "expeditiously" resolve patent disputes and "provid[e] certainty to the applicant, the reference product manufacturer, and the public at large"[61]—has not lived up to the provision's original intent.

Fortunately, the solution to patent dance issues is partially straightforward: pass legislation following the disclosure and patent resolution provisions of the Hatch-Waxman Act.[62] Under Hatch-Waxman, innovators are required to initially list all relevant patents in their new drug applications (NDAs), which then are published in the FDA's Orange Book.[63] A generic manufacturer is then required to disclose any patents that it considers invalid or not infringed as part of the abbreviated new drug application (ANDA) process.[64] Innovators can then initiate infringement suits to protect the relevant patents.[65] Mimicking this scheme in the biosimilar approval process would provide the same benefits of the patent dance without the present drawbacks. Requiring

initial disclosure of a biologic's patents would allow the FDA to publish this information in its Purple Book and obviate the need for applicants to send confidential information to innovators only to await a similar patent list. Moreover, innovators would also be able to bring pre-launch infringement actions regarding those patents at issue.[66]

Foreign Supply Chain Dependence

Both Dr. Siegel and Ms. Guarisco Fildes touched on supply-chain issues and foreign dependence as one potential challenge facing biosimilar access. COVID-19 has demonstrated just how dependent US supply chains have become on foreign inputs.[67] For drugs specifically, US drug manufacturing has shifted overseas: only 28 percent of active pharmaceutical ingredient (API) manufacturers selling into the US market are actually located in the United States.[68] The real issue, Dr. Siegel suggested, is that there is no data tracking how much product any given API manufacturer actually contributes to the total market. For example, we know that 13 percent of all API manufacturers are in China, but we do not know what percentage of all US API products are produced there.[69] Thus, understanding actual production share is critical to understanding and remedying any foreign dependence. For biologic products specifically, there have not yet been any reported shortages due to COVID-19.[70] But should these products follow the trends of their small-molecule cousins, biologics may soon become too dependent on foreign inputs as well. At the very least, better understanding any foreign dependence will reduce the risk of limited access to all biologic products in the future.

Biosimilar Uptake

Even if we overcome access barriers and dramatically increase patient access to biosimilars, those patients (along with providers, insurers, and employers) still must actually choose to use them. Thus, identifying the barriers obstructing biosimilar uptake is also critical to realizing the full benefit of these products.

Education

Until there are FDA-approved interchangeable biosimilars, biologics cannot be substituted with biosimilars once prescribed.[71] Accordingly, increasing uptake requires finding ways to boost patient usage through increased biosimilar prescribing practices. Studies have shown that deficient biosimilar prescribing practices are heavily correlated with a limited understanding and overall awareness of these products.[72] Symposium participants discussed at length how greater patient and prescriber awareness of the safety and availability of biosimilars could overcome stigmas and increase patient use of these lower-cost alternatives. As Secretary Azar noted during the symposium, small molecule generic drugs initially faced the same issues. But by overcoming such stigmas through provider education and cultural acceptance, those barriers were eventually dismantled. Mr. Baker emphasized this same point, concluding that educating all those involved will naturally incentivize prescribers and patients to increase biosimilar use. Thus, one key to increased biosimilar usage lies in education.

Dr. Awsare expressed just how integral education has been in increasing biosimilar usage at Kaiser Permanente:

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Congressman Michael C. Burgess, MD

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After spending nearly three decades practicing medicine in North Texas, Rep. Michael C. Burgess (R-TX) was elected to the US House of Representatives in 2003. He currently serves on the House Energy and Commerce Committee as the Republican Leader of the House Energy and Commerce Subcommittee on Health. He also sits on the Subcommittee on Oversight and Investigations and is a member of the House Rules Committee.

Over the course of his public service, Rep. Burgess has been a strong advocate for health care legislation aimed at reducing health care costs, improving choices, reforming liability laws to put the needs of patients first, and ensuring there are enough doctors in the public and private sector to care for America's patients and veterans. He received his MD from the University of Texas Medical School in Houston and was awarded an honorary Doctorate of Public Service from the University of North Texas Health Sciences Center in 2009.

by focusing on educating providers about biosimilars and the approval process, use there increased to 98 percent. Education begins with simple resources like the FDA's "Health Care Provider Materials" webpage[73] or other more detailed materials on the FDA's website,[74] including similar resources for patients.[75] The Purple Book also serves as a useful reference as providers begin to navigate which biologics and biosimilar alternatives have been approved. Learning about the FDA's rigorous pre-approval and post-market scrutiny will only further understanding and confidence. As providers (and by extension, patients) learn that biosimilars are safe and effective alternatives to costly brand-name biologics, they will begin to overcome stigmas and prescribe these products. Of course, how each organization approaches this education will vary as needs differ, but creating "best practices," as Ms. Hyde suggested, can ensure that patient-provider conversations occur in an accurate, timely, and helpful manner.

In addition to learning *about* biosimilars, patient/provider *confidence* in biosimilar efficacy is also key. As Ms. Hyde pointed out, patients must be convinced that biosimilars will provide the treatment they need. Physician recommendations (a party that patients usually trust) and peer-to-peer testimonial programs could both help increase patient use. More fundamentally, without "earning physician buy-in," prescribers will be less likely to recommend these products for their patients.[76] Here, too, Dr. Awsare's experience at Kaiser Permanente proves dispositive. The organization is avidly focused on analyzing and publishing biosimilar data that helps providers understand just how effective these follow-on products can be. Scandinavian countries, for example, foster prescriber buy-in by involving physicians in the formulary process: physician leaders review clinical and real-world data before signing off on biosimilar products to be added to their organization's formulary.[77] More generally, this emphasizes how important it is for education practices to also focus on pharmacy and therapeutic committees (P&T committees). After all, without gaining the support of P&T committee members, biosimilars will not be placed on formularies, leaving patients to brave the exception process or to stick with higher-cost reference products.[78] By educating patients and prescribers about the safety and efficacy of biosimilars, these groups will naturally want to use them.

Patients and providers are not the only ones needing education. Ms. Hyde pointed out that all major insurers in the arthritis space prefer brand-name biologics to follow-on counterparts.[79] Though the FDA can create simpler approval pathways for biosimilars, it cannot regulate whether insurance companies prefer, cover, or reimburse

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the cost of biosimilars.[80] Instead, educating insurers and explaining cost-saving benefits will only further usage as well. Moreover, employers would benefit from similar education, as Ms. Guarisco Fildes explained. Biologics are the highest cost driver of prescription drugs in their health plans. By educating employers, they will more likely choose plans with access to biosimilars and thus further uptake by plan users.

There is no question policymakers should contemplate further measures to improve biosimilar access and use. Without understanding these products or how they are approved, however, biosimilars will remain the wrongfully branded cousin to their more established brand-name counterparts. Not only will improving an overall understanding of biosimilars increase patient use of already approved biosimilars, but increased understanding will also prepare the health care market to accept new products as they are produced, approved, and marketed. Ultimately this will take time. The rise of generics took years and only came after education and cultural acceptance.[81] Similarly, proactively educating patients, providers, insurers and employers will kickstart this process and help dismantle present stigmas.

Prescribing Incentives

Even if patient, provider, insurer and employer education initiatives are successful, policymakers must examine closely whether there are perverse financial incentives impeding biosimilar use. While practices found to be illegal such as prescriber kickbacks, the arbitrary six percent "buy and bill payment," and rebate walls are not an exclusively biosimilar issue,[82] the same arguments against some of these practices can apply in the biosimilars space. Generally, it is a federal felony for physicians to receive remuneration in exchange for prescribing a drug that will be paid for in whole or in part by federal funding.[83] Those paying the remunerations also commit a felony.[84] Some drug companies have tested these laws to provide prescribing incentives without specific remuneration. One example is a "rebate wall," wherein a manufacturer negotiates the sale of a bundle of products in exchange for a favorable rebate. Though these rebates are an exception to the anti-kickback statute,[85] some brand-name manufacturers leverage their market dominance to obtain a more favorable rebate for these bundled products.[86] To qualify for price savings under some of these agreements, payers must give preferential treatment to brand-name blockbusters or enforce "step therapy" systems in which patients must try brand-name products first before trying lower-cost alternatives.[87] Should a payer purchase a competing drug, for example, it may forfeit any discounts on the entire portfolio.[88] Without the dominant market share or expansive drug portfolio, biosimilar manufacturers cannot match these benefits, allowing biologics to artificially preserve monopoly prices.[89]

Accordingly, any efforts to improve biosimilar uptake should take a close look at any potential perverse prescribing incentives. As Secretary Azar said before the Senate Health,

Education, Labor, and Pensions Committee, "rebate walls can prevent competition and new entrants into systems. … [I]t's using their market power in ways that are not appropriate[.]"[90] The FTC has begun investigating the legality of rebate walls,[91] and many are calling for the agency to continue its efforts.[92] Should the FTC find these practices exclusionary and anticompetitive, it should bring antitrust enforcement actions. At its core, however, the problem requires a legislative solution: as these practices are authorized under the anti-kickback statute, revising those safe harbors to exclude such practices is the first step toward reform. Such a revision would solve the problem in broader strokes and would provide more certainty for all involved.

In addition to removing these prescribing preferences, policymakers could also promote biosimilar use. Many have called for measures of this sort, including shared-savings programs and add-on payments,[93] as current Medicare Part B policies encourage prescribers to use higher-cost products.[94] These policy suggestions would incentivize the use of biosimilars by allowing physicians to share in the savings gained by prescribing biosimilars. Both the Biosimilars Council and the Biosimilars Forum have weighed in on this issue extensively,[95] obviating any need to rehash the benefits of these policies here. Such a system should incentivize the use of biosimilars with great care. Two points in this regard are of note. First, should Congress consider implementing a shared-savings model, it must take great care to make certain that overall spending in the shared model is constrained, rather than several bodies getting a share of a larger pie. Second, as European markets have demonstrated, there must be balanced treatment between innovator and follow-on products to create a sustainable biologic market.[96] It goes without saying that biosimilars cannot exist without originator biologics. Thus, any policies should strive to strike the appropriate balance between promoting

lower-cost alternatives and incentivizing new biologic innovation. Indeed, the genius of the Hatch-Waxman Act and a critical component of that law's success was its ability to create a small-molecule drug market that is still sustainable today.

As policy focuses on liberating the biologic market from misinformation, anticompetitive, and inhibiting practices, the benefits of biosimilars will likely come naturally. Moreover, any policy recommendations should strive to preserve prescriber autonomy to choose the best products for the health and benefit of patients. Shared savings and other financial incentives have the capacity to strike this balance, but the issue must be approached with great care to preserve autonomy and promote sustainability.

Reducing Out-of-Pocket Costs

As competition increases, drug prices should naturally decrease as they have in Europe,[97] and additional legislation may be necessary to target drug pricing specifically. In treatment spaces like cancer, these costs

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can be astronomical, even for an insured patient. To remedy this issue, recent legislation has aimed at broad restructuring.[98] While some version of this legislation may need to be considered in the future, at best it is only a superficial solution. Failing to address the core issues limiting biosimilar access and uptake is, again, like lopping off branches without striking at the roots. Rather, by addressing the issues above, legislators can remove the barriers inhibiting free and fair competition, allowing the market itself to drive prices down and achieve the same goal. This may take longer to achieve, but it will likely create a more sustainable market that benefits the health care system in the long run.

Conclusion

Biosimilars hold the key to managing our country's rising health care costs. With the potential to save patients and the economy tens of billions of dollars over the next decade, policymakers should focus their efforts on improving biosimilar access and use to realize these benefits. Perhaps most importantly, future policies should reflect the delicate balance that Senator Hatch struck through the Hatch-Waxman Act and again through BPCIA: promoting competition and protecting innovation. This report has explored some of the greatest obstacles facing biosimilar growth in the United States and respective policy solutions to overcome those obstacles. To overcome access barriers, legislators must reform the patent dance to remove the unintended uncertainty and anticompetitive practices that have arisen since BPCIA's enactment. To overcome usage barriers, it is critical to educate providers, patients, insurers, and employers, and to realign perverse financial prescribing incentives.

Like most things, achieving these aspirations will take time. There will be temptations to make quicker, superficial changes that temporarily solve the problem yet fail to address core causes. Working towards bipartisan and objective solutions to combat core barriers and implement policies emphasizing competition, autonomy, and innovation, we will see the promises of biosimilars fulfilled in a sustainable market for decades to come

As Senator Hatch wrote earlier this year, "[O]ur work is far from done. Barriers remain....[But t]here is a story here. It is one of power, of bipartisanship. It is a story of compromise, of forward-thinking, and cost-savings—and most importantly, of our getting the job done for patients."[99]

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86 David Balto, *Drug 'Rebate Walls' Should be Dismantled by the FTC's Antitrust Arm*, STAT (Dec. 4, 2018), https://www.statnews.com/2018/12/04/ftc-dismantle-drug-rebate-walls/; Coalition to Protect Patient Choice, *How Rebate Walls Block Access to Affordable Drugs*, THECCP.COM (Mar. 6, 2019), https://www.thecppc.com/single-post/2019/03/06/How-Rebate-Walls-Block-Access-to-Affordable-Drugs; *see also* Samantha DiGrande, *How Will Drug Supply Chain Issues Affect Biosimilar Adoption?*, CENTER FOR BIOSIMILARS (Feb. 5, 2019), https://www.centerforbiosimilars.com/conferences/aam-access-2019/how-will-drug-supply-chain-issues-affect-biosimilar-adoption; Doyle, Barlow, & Mazard PLLC, *Consumer Groups Raise Rebate Wall Concerns with Regards to AbbVie/Allergan Merger*, ANTITRUST LAWYER BLOG (Feb. 19, 2020), https://www.antitrustlawyerblog.com/consumer-groups-raise-rebate-wall-concerns-with-regards-to-abbvie-allergan-merger/.

87 Coalition to Protect Patient Choice, *supra* note 86; *see also* DiGrande, *supra* note 86; Doyle, Barlow, & Mazard PLLC, *supra* note 86.

88 Balto, *supra* note 86.

89 DiGrande, *supra* note 86; *see also, e.g.*, Doyle, Barlow, & Mazard PLLC, *supra* note 86 (describing AbbVie's use of rebate walls to protect its "blockbuster drugs, Humira and Skyrizi," leading to higher drug prices and artificially decreased success for competitors); Coalition to Protect Patient Choice, *supra* note 86 (describing Pfizer's litigation against Johnson & Johnson for its exclusionary reimbursement practices that have burdened Pfizer's biosimilar product).

90 *Prescription Drug Pricing*, C-SPAN.ORG (Jun. 12, 2018), https://www.c-span.org/video/?446791-1/secretary-azar-testifies-prescription-drug-pricing-plan.

91 Doyle, Barlow, & Mazard PLLC, *supra* note 86.

92 *E.g.*, Balto, *supra* note 86 (citing biosimilar manufacturer efforts to bring antitrust suits for rebate practices and calling for the FTC to get involved).

93 *E.g.*, ALEX BRILL, MATRIX GLOBAL ADVISORS, PAYOR STRATEGIES TO PROMOTE BIOSIMILAR UTILIZATION (2016); Allison Inserro, *Shared Savings, Add-on Payments Could Save Medicare Billions, Biosimilars Forum Says*, CENTER FOR BIOSIMILARS (May 30, 2019), https://www.centerforbiosimilars.com/news/shared-savings-addon-payments-could-save-medicare-billions-biosimilars-forum-says-; Anna Rose Welch, *Why It's Time for a U.S. Biosimilar Shared Savings Model*, BIOSIMILAR DEVELOPMENT (Jun. 17, 2020), https://www.biosimilardevelopment.com/doc/why-it-s-time-for-a-u-s-biosimilar-shared-savings-model-0001.

94 Welch, *supra* note 93.

95 *E.g.*, ALEX BRILL, MATRIX GLOBAL ADVISORS, SHARED SHAVINGS DEMONSTRATION FOR BIOSIMILARS IN MEDICARE: AN OPPORTUNITY TO PROMOTE BIOLOGIC DRUG COMPETITION (2020) [http://www.getmga.com/wp-content/uploads/2020/05/Biosimilar_Shared_Savings.pdf]; *see also* Welch, *supra* note 94.

96 *See* REILLY & SCHNEIDER, *supra* note 81 (discussing studies done in Europe, finding that "[a] level playing field between all participating manufacturers is the best way to foster competition; mandatory discounts which place artificial downward pressure on manufacturers do no engender a sustainable market environment.").

97 *See generally id.*

98 *E.g.*, H.R. 3, 116th Cong. (2019).

99 Hatch, *supra* note 31.

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