

A New Trend in Trade Agreements: Ensuring Access to Cancer Drugs

By Maria Fabiana Jorge*

Abstract

A World Health Organization (WHO) report on cancer indicates that the cancer burden will increase at least by 60% over the next two decades, straining health systems and communities. Companies develop cancer drugs in part because payers are less resistant to paying high drug prices for these drugs. As Barbara Rimer, Dean of the University of North Carolina and Chair of the U.S. President’s Cancer Panel stated, “[m]ost cancer drugs launched in the United States between 2009 and 2014 were priced at more than \$100,000 per patient for one year of treatment.” Many of the new cancer drugs are biologics. Such prices are clearly out of reach for most patients who will need them increasingly more to stay alive. While competition is critical to ensure lower drug prices, we have seen a number of strategies, including through trade agreements, to prevent competition and extend monopolies over these drugs and their very high drug prices. It is no accident that the exclusivity granted to biologic drugs has been one of the most conflictive provisions in recent trade agreements such as the United States-Mexico-Canada Agreement (USMCA) and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). Nevertheless a new trend in trade agreements started in 2007 when U.S. Members of Congress pushed back against the interests of powerful economic groups seeking longer monopolies for drugs. These Members of the U.S. Congress prevailed then in restoring some balance in the trade agreements with Peru, Colombia and Panama and further consolidated this new trend in 2019 in the USMCA. Moreover, following the U.S. withdrawal from the original Trans-Pacific Partnership (TPP), the negotiators of the remaining 11 countries also pushed back to ensure a better balance between innovation and access in the CPTPP. People around the world need to be aware of these precedents and ensure that they also work for access to medicines for their own citizens.

Un rapport de l'Organisation mondiale de la santé (OMS) sur le cancer indique que la charge que représente cette maladie augmentera d'au moins 60 % au cours des deux prochaines décennies, mettant à rude épreuve les systèmes de santé et les communautés partout dans le monde. Les entreprises pharmaceutiques développent des médicaments contre le cancer en partie parce que les patients sont moins réticents à payer des prix élevés pour les obtenir. Comme l'a déclaré Barbara Rimer, doyenne de l'université de Caroline du Nord et présidente du groupe d'experts sur le cancer de la présidence des États-Unis, « la plupart des médicaments anticancéreux lancés aux États-Unis entre 2009 et 2014 a coûté à chaque patient plus de 100 000 dollars pour une année de traitement ». Un grand nombre de ces nouveaux médicaments contre le cancer sont des produits biologiques. Le coût que représente leur achat est clairement hors de portée de la plupart des patients alors qu'ils sont nécessaires pour leur permettre de rester en vie. Si la concurrence est essentielle pour garantir les prix les plus bas, un certain nombre de stratégies ont été mises en œuvre par les entreprises concernées, notamment par le biais d'accords commerciaux, pour empêcher la concurrence, étendre leur monopole sur ces médicaments et maintenir des prix très élevés. Ce n'est pas par hasard si la durée de l'exclusivité accordée aux médicaments biologiques a été l'une des dispositions les plus discutées dans les accords commerciaux conclus récemment, notamment l'accord conclu entre les États-Unis, le Mexique et le Canada (USMCA) et l'Accord de partenariat transpacifique global et progressiste (PTPGP). Toutefois, une nouvelle tendance est apparue concernant les accords commerciaux à partir de 2007, lorsque les membres du Congrès américain ont refusé de protéger les intérêts de puissants groupes économiques qui cherchaient à prolonger la durée maximale du monopole conféré par les brevets qu'ils détenaient sur les médicaments, parvenant ainsi à rétablir un certain équilibre dans les accords commerciaux conclus avec le Pérou, la Colombie et le Panama. Cette tendance s'est confirmée en 2019 dans le cadre de l'accord conclu entre les États-Unis, le Mexique et le Canada. Par ailleurs, à la suite du retrait des États-Unis du premier traité relatif au Partenariat transpacifique, les négociateurs des 11 pays restants ont également fait pression pour assurer un meilleur équilibre dans le PTPGP entre l'innovation et l'accès aux médicaments. Partout dans le monde, les gouvernements doivent être conscients de ces précédents et veiller eux aussi à garantir à leurs citoyens un meilleur accès aux médicaments.

Un informe de la Organización Mundial de la Salud (OMS) sobre el cáncer indica que la carga del cáncer se incrementará al menos en un 60 % durante las próximas dos décadas, y llevará al límite a los sistemas de salud y las comunidades. Las empresas desarrollan medicamentos para el cáncer en parte porque las personas que los compran se resisten menos a pagar precios elevados por ellos. Como señala Barbara Rimer, decana de la Universidad de Carolina del Norte y presidenta del Panel del cáncer de la Presidencia de los EE.UU., “[l]a mayoría de los medicamentos para el cáncer que se han lanzado en los Estados Unidos entre 2009 y 2014 tenían un precio de más de 100 000 dólares por paciente para un año de tratamiento”. Muchos de los medicamentos nuevos para el cáncer son biológicos. Obviamente, esos precios están fuera del alcance de la mayoría de los pacientes que los necesitarán cada vez más para permanecer con vida. Aunque la competencia es fundamental para garantizar un precio más bajo de los medicamentos, hemos observado diversas estrategias, entre ellas el uso de acuerdos comerciales, para evitar la competencia, ampliar los monopolios sobre estos fármacos y mantener sus precios tan elevados. No es casualidad que la exclusividad otorgada a los medicamentos biológicos haya sido una de las disposiciones más conflictivas en acuerdos comerciales recientes como el Tratado entre México, Estados Unidos y Canadá (T-MEC) y el Tratado Integral y Progresista de Asociación Transpacífico (TIPAT). Sin embargo, en 2007 comenzó una nueva tendencia en los acuerdos comerciales, cuando algunos miembros del Congreso de los EE.UU. se opusieron a los intereses de grupos económicos poderosos que buscaban un mayor monopolio sobre los medicamentos. Por aquel entonces, estos miembros del Congreso de los EE.UU. consiguieron restablecer un cierto equilibrio en los acuerdos comerciales con el Perú, Colombia y Panamá, y consolidaron más esta nueva tendencia en 2019 en el T-MEC. Asimismo, tras la retirada de los EE.UU. del Acuerdo de Asociación Transpacífico (TPP) original, los negociadores de los 11 países restantes también se impusieron para garantizar un mayor equilibrio entre la innovación y el acceso en el TIPAT. Los dirigentes de todo el mundo deben conocer estos precedentes y han de procurar también trabajar con miras a acceder a medicamentos para sus propias sociedades.

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A sobering look at the increase of cancer cases and the inequitable access to medications to treat the disease

The World Health Organization recently published a sobering report on cancer that puts in evidence the challenges countries face to treat this serious disease. Report data provides some perspective on the uphill battle governments and patients face and will increasingly face in the years to come. Indeed, “[i]n 2018, 18.1 million people around the world had cancer, and 9.6 million died from the disease. By 2040, those figures will nearly double.” ... Cancer is the cause of about 30% of all premature deaths from NCDs among adults aged 30-69.”¹

Furthermore, the report identifies key messages for policy-makers, including:

1. *Globally the cancer burden will increase by at least 60% over the next two decades, straining health systems and communities. Cancer is a significant, growing concern. It is already responsible for one in six deaths globally, and the burden on individuals, communities, health systems and economies will continue to increase.*²
2. *There have been rapid advances in cancer diagnosis and treatment, however...access to effective services has been profoundly inequitable...*³

Indeed, the report highlights the inequitable treatment for this illness:

*“Many low-and middle-income countries already have large numbers of cancer patients who do not have access to timely, quality diagnosis and comprehensive treatment. In 2019, more than 90% of high-income countries reported that treatment services for cancer were available in the public health system, compared to less than 15% of low-income countries, where survival is unacceptable low.”*⁴

While the report addresses a number of areas that could help to prevent and treat cancer, it also highlights the issue of high-price of medicines in the following terms:

“Health authorities should restrict direct promotion of cancer products to clinicians and patients and promote the use of generic and biosimilar medicines as appropriate.” And,

*“In 2018 WHO launched an initiative to save the lives of millions of children from cancer and in 2019 we prequalified a biosimilar medicine for the first time, trastuzumab, paving the way for more women to have access to one of the most effective but most expensive breast cancer treatments.”*⁵

Companies develop cancer drugs in part because payers are less resistant to paying high drug prices for these drugs

As stated by Barbara Rimer, dean of the University of North Carolina and Chair of the U.S. President’s Cancel Panel , “[m]ost cancer drugs launched in the United States between 2009 and 2014 were priced at more than \$100,000 per patient for one year of treatment. More recently, we’ve seen launch prices of more than \$400,000 for a year of treatment.”⁶ Interestingly enough, a 2017 study of the United States Government Accountability Office (GAO) on the Drug Industry concluded that “oncology drugs were among the most frequently approved in all but 2 years from 2005 through 2016.”⁷ Indeed, out of the “263 drugs approved by FDA in 2016, the most common product categories were oncology (55 approvals) and metabolism and endocrinology (38 approvals). With regards to the 22 novel drug approvals in 2016, the most common product categories were oncology (5 approvals) and neurology (4 approvals). Nevertheless, the report also seems to note a correlation between the development of cancer drugs in part because payers are less resistant to pay higher prices for these drugs: “Companies also seek to maximize potential revenues by investing in the development of drugs that can command high prices [...]Expectations about payer reimbursement could also influence potential pricing and investment decisions according to some experts. For example, one expert noted that payers typically do not resist high prices for oncology drugs.”⁸

Below are a few examples of cancer drugs with 6 figure prices⁹:

Drug	Manufacturer	Indication	Annual Per-Patient Expenditure (\$) AWP
Cyramza	Eli Lilly	Metastatic Colorectal Cancer	220,320
Avastin	Genentech	Metastatic Renal Cell Carcinoma	149,893
Yervoy	BMS	Metastatic Melanoma	143,838
Kadcyla	Genentech	HER2+Metastatic Breast Cancer	181,056
Erbitux	Imclone/Eli Lilly	Head-and-Neck Cancer	166,679
Oncaspar	Baxalta	Acute Lymphoblastic Leukemia	387,864

All these drugs are biologics, the use of which has become an essential component for the treatment of cancer.¹⁰ These are complex drugs originated from living organisms for the treatment of critical illnesses such as cancer, genetic disorders and anti-immune diseases. They are also some of the most expensive drugs in the market. Interestingly enough, the WHO report addresses the need of ensuring the affordability of cancer-related health products including “creating competition among therapeutically similar medicines, including generic and biosimilars; and using voluntary license agreements and applying the flexibility of TRIPS for patented medicines, when appropriate.”

It is critical to have a legal framework to encourage competition (and lower prices) by supporting the early launch and uptake of biosimilars

The need to generate more competition of biosimilars¹¹ as a way to lower prices is also one of the pillars of the U.S. Food and Drug Administration Biosimilar Action Plan. In this sense, former FDA Commissioner stated: “To make sure that the next generation of breakthroughs remain affordable, it requires a vibrant competition from biosimilars.”¹²

But contrary to efforts to increase drug competition through the launch of both generics and biosimilars, some of the provisions being sought by some in trade agreements, would have done exactly the opposite by granting longer monopolies and in fact delaying or deterring competition for these critical drugs. That is the case for long exclusivity periods for undisclosed test or other data related to biologic products on top of the 20-year patent term and in some countries, the possibility of also granting patent term extensions

Trade Agreements: a tool to delay or prevent competition of biosimilars?

It is no secret that in two of the most recent trade negotiations such as the regional Trans Pacific Partnership, which became the Comprehensive and Progressive Agreement for Trans-Pacific Partnership and the United States, Mexico, Canada Agreement (USMCA) the issue of biologics, new in trade agreements, turned into one of the most conflictive provisions of the agreements. Indeed, some interest groups implemented a significant effort to include specific biologic exclusivity provisions in the TPP which originally required Parties to grant 5 or 8 years of exclusivity for biologics. Something very similar happened in the USMCA which concluded (in its original version) with an exclusivity for biologics of 10 years. In both cases, however, such exclusivity was either suspended or eliminated in subsequent renegotiation processes.

Trade agreements should not prevent or delay drug competition

After about more than two decades since the implementation of the Agreement on Trade Related Aspects

of Intellectual property Rights (TRIPS) countries are experiencing the perils of adopting increasingly higher IPR provisions. In fact, in the two major trade agreements mentioned above there have been a clear push back because not even the richest country in the world is able to pay for these expensive drugs. Those two trade agreements also had an important bipartisan precedent, the New Trade Policy or May 10th Agreement of 2007.

What it is at risk is very serious: whether patients will be able to access critical drugs such as those for the treatment of cancer. Countries may want to pay attention to this new trend in trade agreements, which refuse to provide additional monopolies to powerful lobbying groups at the expense of the health of their citizens. Indeed, very powerful economic groups are championing longer and broader monopolies for drugs. A recent article published by Wall Street Journal investigative reporters highlights the power of these groups which, however, are losing their influence over decision markets. The article specifically refers to the USMCA where the U.S. Congress stripped provisions “backed by PhRMA to keep certain top-selling drugs free from competition for year.”¹³

“PhRMA’s lobbying force is among Washington’s biggest. It has 47 lobbying firms on retainer and 183 registered lobbyists. It employs lawyers, economists, political strategists, pollsters, media advisers and other consultants. PhRMA’s budget is double that of the oil industry’s Washington trade organization. One division spends tens of millions a year to recruit doctors, seniors and patients who have benefited from drugs to lobby Congress.

So far in the 2020 campaign, the industry has donated \$7.5 million to lawmakers, mostly to Republicans, data from the nonpartisan Center for Responsible Politics show, including Senate Majority Leader Mitch McConnell of Kentucky and House Republican Leader Kevin McCarthy of California.”

Not only that, the article also states that “PhRMA’s budget grew to \$456 million in 2017 from \$271 million in 2016, tax records show.”

There are two important caveats, however: a) this data only refers to the money spent in the United States where there are transparency laws, but more resources are invested in the effort to lengthen and broaden monopoly rights in other countries; and b) this does not include the resources devoted by BIO, the lobbying organization for the biotechnology industry or individual companies.

Nevertheless, decision makers are saying enough is enough and are setting a new trend in trade agreements to prevent the adoption of provisions that would further delay or deter competition for these drugs. Competition is, indeed, the key to lower drug prices.

A new trend in trade agreements to preserve competition for these very expensive drugs

As mentioned above, both the TPP/CPTPP and the USMCA were substantially changed even after their negotia-

tion had been wrapped up. Indeed, in the case of the TPP, following the U.S. withdrawal, the remaining 11 countries decided to suspend several provisions including exclusivity for biologic drugs, exclusivity for small molecule drugs, patent term extensions and the broadening of what constitutes patentable subject matter. Similarly, the U.S. Congress demanded changes in the USMCA as a condition for ratifying the agreement, which eliminated the exclusivity granted to biologic products, among others. There were a number of concerns with this article beyond the period of exclusivity including the actual definition of what constitutes a biologic product, when the exclusivity would start and even a footnote that could have extended the exclusivity for some products that were expected to transition to biologics in March 2020. At the end, the U.S. Congress and the Office of the U.S. Trade Representative agreed to eliminate the article in its entirety, reduce the exclusivity granted for small molecules, eliminate the broadening of patentable subject matter, include conditions and limitations to patent term extensions and improve the regulatory review exception (Bolar) as well as include rewards for the launch of generic/biosimilar drugs.

This bipartisan agreement to eliminate the exclusivity for biologics was also fully consistent with the conclusions reached by the United States Federal Trade Commission which considered that no exclusivity is needed for these drugs as patents provide sufficient protection.¹⁴ As some have been pointing out, the effort to include long exclusivity periods for biologics in trade agreements seeks to tie the hands of Members of Congress so that when drug spending becomes unsustainable due to increasing biologics' utilization, Congress will be unable to reduce the exclusivity period as trade agreements, which are international law, super-

sede national law.¹⁵ Thus, if Congress were to reduce the exclusivity in the country below the period established in the trade agreement it would be in violation of the agreement.

It is expected that as more patients are prescribed biologic drugs, the additional budgetary pressures will be unsustainable. Former FDA Commissioner Scott Gottlieb put things into perspective:

*"[w]hile less than 2 percent of Americans use biologics, they represent 40 percent of total spending on prescription drugs." Moreover, as more biologics are increasingly prescribed, "[b]iologics represent 70 percent of the growth in drug spending from 2010 to 2015. And they're forecasted to be the fastest growing segment of drugs spending in the coming years."*¹⁶

Therefore, if governments and payers want to afford biologic cancer drugs which are critical for the successful treatment of this deadly disease, it is essential that they increase competition for these very expensive drugs by creating legal systems that support not only their development but also the early launch and competition of biosimilars. Hence, it is essential that countries do not commit to granting even longer monopolies for these drugs in trade agreements.

The table below identifies some of the changes introduced in three important trade agreements showing this new policy trend with regards to pharmaceuticals. These agreements should serve as a guide to build on for future ones. Indeed, as stated by USTR Amb. Lighthizer with regards to the last trade agreement, "the USMCA represents the gold standard in U.S. trade policy and will be the template for U.S. trade agreements going forward."¹⁷ Speaker Pelosi also made similar statements as to the fact that the USMCA would become a new template for future trade agreements.¹⁸

Provision	New Trade Policy (NTP) or May 10 th Agreement	Comprehensive and Progressive Agreement for the Trans-Pacific Partnership	USMCA
Patent Linkage	No mandatory patent linkage	No mandatory patent linkage	No mandatory patent linkage
Patent Term Extensions for Delays in the Granting of the Patent	No mandatory patent terms extensions for pharmaceuticals	No mandatory extensions	Yes but countries can set conditions and limitations
Patent Term Extensions for Delays in the Regulatory Office	No mandatory extensions for pharmaceuticals	No mandatory extensions	Yes but countries can set conditions and limitations
Exclusivity for Small Molecule Drugs	Period that would normally mean 5 years. Period can be concurrent to that of the first country	No	At least 5 years
Exclusivity for Biologic Drugs	No	No	No
Broad Bolar Provision	Yes but not mandatory	Yes, mandatory	Yes, mandatory
Incentives/Rewards for the launch of generics/biosimilars	In some circumstances	No	Yes

As countries engage in new trade negotiations they should look carefully at this trend rejecting higher IP protections and looking at how to further foster balance in their laws and regulations to ensure the development of new drugs and their affordability as the effectiveness of these medicines will depend on whether they are accessible to the population.

TRIPS Flexibilities need to be complemented

The WHO Report mentioned above, also addresses the need to utilize the flexibilities of the TRIPS Agreement for patented medicines, when appropriate. Indeed, it is critical to adopt balanced intellectual property provisions that incentivize both innovation and access. However, while the flexibilities provided under the TRIPS Agreement must be preserved and respected, countries that have applied it or even considered applying some of them, for instance compulsory licensing, have been under enormous pressure to waive them. That was the case of India which issued only one compulsory license but which has been the subject of many pressures including in the Special 301 Report of the Office of the United States Trade Representative.

Thus, TRIPS flexibilities, while very important, are not enough to address the problem of access to these very expensive drugs. Much more needs to be done. Hence, besides preventing the inclusion of long exclusivities in trade agreements, countries should also adopt a number of other provisions including a broad regulatory review process or Bolar provision to allow the development of biosimilars during the term of the patent so as to be able to launch a product immediately after patent expiration, incentives for the development, launch and uptake of biosimilars and penalties for those that misuse intellectual property rights and/or resort to filing frivolous lawsuits simply to delay or deter competition from generics or biosimilars. For instance, in the U.S., while the FDA made a significant effort to approve biosimilars out of 26 biosimilars approved by February 2020, only 16 had been launched. While the reasons for the failure to launch are varied it seems that in many cases biosimilars approved by FDA cannot be launched due to litigation initiated by originator companies or because they have reached a settlement agreement as a result of litigation.

Commissioner Gottlieb also expressed concerns over competition for these complex pharmaceuticals in the following terms:

“Competition is, for the most part, anemic.”...

“It is anemic because litigation has delayed market access for biosimilar products that are, or shortly will be, available in markets outside the U.S. several years before they’ll be available to patients here. These delays can come with enormous costs for patients and payors.”¹⁹

But not all is bad news. As mentioned above, little by little decision markets are becoming aware of the

negative consequences of some intellectual property provisions included in trade agreements. It is important to pay attention to this new trend and to determine what else should be done to secure a fair system for both originator and generic/biosimilar companies and above all for consumers.

Conclusion

The WHO report on cancer presents a very sobering picture about how this disease is expected to grow in the years to come (60% in the next 20 years). Biologic drugs are critical for the treatment of cancer and other diseases. Many times each of these drugs cost several hundred thousand dollars per person per year. While some powerful interest groups are seeking to include new provisions extending and broadening their monopolies in trade agreements, three agreements show a new trend that reflects that decision makers are rejecting such efforts and striving to preserve competition for these very expensive drugs to lower drug prices. More needs to be done to increase access to medicines but following the example of these recent trade agreements is a first important step.

Endnotes:

¹ WHO Report on Cancer, Setting Priorities, Investing Wisely and Providing Care for All, 2020, page 13.

² WHO Report on Cancer, Setting Priorities, Investing Wisely and Providing Care for All, 2020, page 17.

³ WHO Report on Cancer, Setting Priorities, Investing Wisely and Providing Care for All, 2020, page 17

⁴ WHO Report on Cancer, Setting Priorities, Investing Wisely and Providing Care for All, 2020, page 12.

⁵ WHO Report on Cancer, Setting Priorities, Investing Wisely and Providing Care for All, 2020, page 12.

⁶ Barbara K. Rimer, Dr.P.H., dean of the University of North Carolina’s Gillings School of Global Public Health, Chair of the President’s Cancer Panel, U.S. National Institute of Health, National Cancer Institute, “The Imperative of Addressing Cancer Drug Costs and Value”, March 15, 2018

⁷ United States Government Accountability Office, Drug Industry – Profits, Research and Development Spending, and Merger and Acquisition Deals, November 2017, page 44.

⁸ United States Government Accountability Office, Drug Industry – Profits, Research and Development Spending, and Merger and Acquisition Deals, November 2017, pages 44-45.

⁹ America’s Health Insurance Plans (AHIP), High-Priced Drugs: estimates of Annual Per Patient Expenditures for 150 Specialty Medications, April 2016.

¹⁰ Andrew D. Zelenetz, MD, PhD; Islah Ahmed, MD; Edward Louis Braud, MD; James D. Cross, MD; Nancy Davenport-Ennis; Barry D. Dickinson, PhD; Steven E. Goldberg, MD, MBA; Scott Gottlieb, MD; Philip E. Johnson, MS, RPh; Gary H. Lyman, MD, MPH, FRCP(Edin); Richard Markus, MD, PhD; Ursula A. Matulonis, MD; Denise Reinke, MS, NP; Edward C. Li, PharmD, BCOP; Jessica DeMartino, PhD; Jonathan K. Larsen, MPP; and James M. Hoffman, PharmD, MS, BCPS

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¹¹ FDA defines biosimilars as: “A **biosimilar** is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product.” <https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products> - accessed on February 25, 2020.

¹² Scott Gottlieb, M.D., Remarks from FDA Commissioner as prepared for delivery at the Brookings Institution on the release of the FDA’s Biosimilars Action Plan, July 18, 2018.

¹³ Brody Mullins and Stephanie Armour, The Drug Lobby Loses Potency With Lawmakers, The Wall Street Journal, February 20, 2020.

¹⁴ U.S. Federal Trade Commission, Emerging Health Care Issues, Follow-on Biologic Drug Competition, June 2009.

¹⁵ Maria Fabiana Jorge, Biologics and Trade Agreements: Defining the new frontier, Journal of Generic Medicines, May 5, 2014 (online first version).

¹⁶ Scott Gottlieb, M.D., FDA Commissioner, Remarks as prepared for delivery at the Brookings Institution on the release of the FDA’s Biosimilars Action Plan, July 18, 2018.

¹⁷ <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2019/december/ambassador-lighthizer-issues-statement-house-passage-usmca>

¹⁸ Politico Pro, Pelosi: USMCA will be template for future deals, “It would be a prototype, a template for future trade agreements recognizing that global is a fact of life. It is inevitable,” she said at the Wall Street Journal CEO Council tonight.” December 9, 2019



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¹⁹ Scott Gottlieb, M.D., FDA Commissioner, Remarks as prepared for delivery at the Brookings Institution on the release of the FDA’s Biosimilars Action Plan, July 18, 2018.

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