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Innovations for Successful Societies, Bendheim Hall, Princeton University
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LaForge: This is Gordon LaForge with Innovation for Successful Societies speaking with Tatiana Andía in Bogata, Columbia on September 3, 2018. Tatiana Andía is assistant professor in the Department of Sociology at the University of Los Andes in Bogota and served as Advisor to Colombia's Minister of Health Alejandro Gaviria Uribe. Thank you for speaking with us. Would you tell us a little bit how you came into the field of health?

Andía: *My undergraduate academic background is in Economics, I studied Economics here at Los Andes (a private research university) and I did a second BA in the U.S., in History. But then, when I graduated, I started working in development. I went to the LSE (London School of Economics) to do a Masters in Development. And when I was there, I took a class in Global Political Economy, and I met Ken Shadlen (Professor of Development Studies, LSE), whose research was in intellectual property and access to medicines. And at the time we were negotiating in Colombia a free trade agreement with the U.S., and intellectual property was one of the big issues.*

Before I left LSE, I was able to work in the economics department on a project that was trying to measure the impact of the free trade agreement with the U.S. on access to health. So, I ended up being in health through the issues of free trade agreements and intellectual property in the health system. My master's thesis at the LSE was in that and global movements of access to medicines.

When I came back to Colombia, I worked on access to water at the National Planning Department and at Los Andes in the developmental study center. I did mostly development, but I remained interested in health issues. I decided to go and pursue a PhD in sociology but remained involved in civil society discussions on access to medicines. My dad, a doctor, is a big activist on access to medicines, and so, through him and his network I was always involved with the issues.

Everyone was focused on intellectual property, because that was a priority for international NGOs like Public Citizen, like MF, like Oxfam. … But for my PhD I wanted to focus on the political economy of generics (drugs—for example, the barriers of entry for generics and ways in which generics are not used in countries like Colombia. I ended up studying the political economy of biosimilars, (biopharmaceuticals that have active properties similar to drugs previously been licensed) as well. I tried to do many things. One was to look at the scientific debates and the ways in which policymakers figure out how to do things, how to conform with international

standards while at the same time balancing it with what the country needs.

In the case of Colombia, I think we challenge international standards on some issues. To give you an example, in Colombia, for a long time we conformed closely with international guidelines on IP, on intellectual property. But the patents office was very stringent on the requirements for novelty. They didn't patent many things that other patent offices in the Andean region protected, even though Andean countries operated at the time under the same patent law. So, that's one example. So, you conform, but then you do something else.

And then, I was very concerned with when you don't conform because the international standard doesn't suit you and you challenge an international standard. That is very difficult. I studied Brazil and Colombia – Brazil on intellectual property issues for generics and for antiretroviral medicines, and here with the biosimilar and biologics regulations.

At the time, [the policies were] very revolutionary. With Brazil, you say, "Okay, it's a big country, it generally challenges international issues. It's normal." But with Colombia, historically the government challenged international norms less. [But Colombia began to change its policies.] I think the finances of the healthcare system explain half of what happened. I think in the case of Colombia, the issue of right to health and the huge challenges that the country has in terms of financing health and being able to finance a very ambitious and universal healthcare system, gave a lot of ground to policymakers for innovation and creativity opening spaces that had been completely closed.

So, I think there were political opportunities that lack of money gave civil servants to think outside the box about how to lower pharmaceutical prices. One way was to regulate prices but the other was to reform the structure of decision making and eliminate incentives for purchasing high cost drugs. The health policy people were able to sell the idea to both the economists at the Ministry of Finance, but also to the economists that were, at that time, working at the Ministry of Health.

The structural change has a lot to do with Colombia having always had an administration of the healthcare system by doctors, by health professionals. But there were two moments in which economists

helped define new directions. One economist was Juan Luis Londoño, (Minister of Health and Deputy Chief of the National Planning Department in the 1990s], who was the architect of the country's social protection system. MCI. He had an inspiration on how we should manage healthcare. [He reduced fragmentation, introduced managed competition, and increased performance-based accountability.]

But then the next minister of health was a physician, and basically the finances went crazy.

When the economists came back they began to deal with the whole issue of financial sustainability and the huge deficits in healthcare. They were thinking about it in terms of economics.

The argument for competition is easy to sell to an economist. So the two things in terms of pharmaceuticals or pharmaceutical policies that were done at the time were price regulation and the promotion of competition. On the one hand, price regulation – even if the economists generally don't like it--is necessary when the market is as crazy as the pharmaceutical market is. On the other hand, competition is something that an economist thinks should exist. Physicians think any barrier sounds awful and argue that the barriers are all necessary because it's about safety and efficiency, and confidence by patients and so on. But economists don't think about that. They think market competition is the best solution.

So I think all of that made the environment perfect for the kind of reforms that were undertaken in the last six to eight years.

LaForge: To set the scene for your involvement, what was the argument that your father was making as an activist? What was his role?

Andía: *His role was more important than he even thinks, because he was saying for a long time that the prices of high-cost drugs were making the system unsustainable—that if you continue to give a small number of people very costly medicines, you would undermine the financing of the whole basic health package…*

LaForge: And therefore, access for everyone.

Andía: *And therefor access for everyone. You would diminish expenditure that was most needed as well as preventive care, and instead finance an extra two months of bad quality-of-life for an end-of-life cancer patient. But he was not focused on the internal decision-*

making of the healthcare system and how decisions were made to allocate those resources, he was more concentrated on the role that the pharmaceutical industry was playing by also charging prices that were far higher than in other countries.

So, he was the first one who did a comparison. The first comparison was with Spain. He was like, "Okay, Spain is a country that is more developed than us, and it is paying, sometimes, 100 percent less on some drugs. And so, this doesn't make sense, right? And so, we're paying too much, and at too much of a higher price rate."

So that was his argument, and he was very compelling. There was a small financial crisis in the healthcare system in Colombia at the end of [President Alvaro] Uribe's time. They declared a social emergency and issued something like 14 decrees. One of them was private regulation, another one was limiting the right to health in order to limit the tutelas [lawsuits to require the government to cover items and services not in the benefits package].

Patients and their doctors mobilized, especially high-cost patients: cancer patients, organ list patients, rheumatoid arthritis patients were very well-organized. They created an umbrella organization that was called Pacientes Colombia – Colombian Patients.

They marched, and yes, they did everything – with doctors as well. And one day they marched to the constitutional court, and they said, "We don't have executive power. We don't have the government, but we do have the court." They marched with adds that read: "Health is not a favor, health is a right." And of course, the court found all those decrees and the social emergency unconstitutional and everything collapsed.

So, when the new [Juan Manuel] Santos government came in [in 2010], there was a financial crisis with no solution whatsoever at hand. That's when the most compelling argument was that we're spending really badly and one of the most outrageous things is paying a lot for very expensive medicines for only few people.

LaForge: So basically, because the decrees failed and the constitutional court ruled the way it did, the only way to handle this crisis was to improve efficiency in the system. Everyone had to find ways to do this.

Andía: *Yes. And what was very evident at that time, something that I think is really hard for a foreigner to understand, is there's no way we can limit the right to health. It's something that has been done even in*

Brazil, where the court is also progressive and the right to health has a long presence and it's written in the constitution. In Colombia, it's not written in the constitution [but the court ruled that the wording of the constitution implied such a right and it partially struck down aspects of the legislation intended to define and limit the right introducing cost-effectiveness criteria]. So at that time it was evident that limiting the right to health was not feasible, and you needed to do something else: gather more resources, use the ones you have more efficiently somehow, try to cut some costs and maybe try to impose some new taxes on new things.

In Santos's second term, the government had to address a situation in which health was a right, everything under the sun was covered, and doctors were completely autonomous. We did not want to cover things where there was no scientific evidence of effectiveness, but the courts allowed alternative treatments, even if there was little evidence, including financing Dolphin Therapy for autism.

The court said, "If the doctor says the kid needs it, well, we can only give it because it's a matter of life or death."

LaForge: And the doctors do not have incentives to provide these services.

Andía: *Exactly. And that's the second. Later on, something that we wanted to work on was the relationship between the pharmaceutical industry and doctors, patients, hospitals, and the media.*

LaForge: The media?

Andía: *Yes.*

LaForge: To do what? Just socialize this information?

Andía: *Yeah exactly, like a copy of the U.S. Sunshine Act. So, basically, that the pharmaceutical companies have to report every transfer of money, or gifts, or trips, or whatever that they give to a physician, to a healthcare professional, or patient. And it's basically a transparency measure so that we then can use that information to make evident that doctors have some conflicts of interest coming up.*

LaForge: So how did you come to be involved in the team that Claudia Vaca (professor, National University of Colombia, Master of Pharmacy) put together?

Andía: *I met Claudia Vaca a long time ago, because she was part of the movement for access to medicines that I was also engaged with. But we weren't friends. We knew each other, I would say. She was the key informant for the theoretical framework in my Ph.D. dissertation, because she is the expert on bioequivalence and biosimilarity, the things that I was studying.*

So Claudia Vaca was, at the time, working at the Ministry of Health, and so I came to see her, and she said "We're doing the draft on biologicals, it would be great if you could come and see the meetings," and so on. Claudia Vaca asked the minister and the team whether she could give me access to the meetings to help advance my research in exchange for working on price regulation, since I knew all about that. It was a fair deal. And so, that's how it happened, and I ended up being involved in everything.

LaForge: What year was this?

Andía: *At the end of 2013, beginning 2014.*

LaForge: So, at this point, they were done with...

Andía: *With the methodology. So, I was there for the second implementation of the methodology, but I wasn't involved in the creation of the methodology or in the first debates with the industry. I came only for the implementation.*

LaForge: And what do you remember the biggest obstacles being to the implementation?

Andía: *The first challenge was the data, the handling of the data. The person in charge of the dataset declined to share it and treated it as proprietary. The same was true of other people who controlled information. They did not share.*

Alejandro Gaviria, because he was a professor, brought some of his most brilliant students to the ministry to help him. But access to the data and the formulas was limited – he was the minister – even for his team access to the data was limited. For example, one of the persons that he hired – he's now finishing a PhD in Economics – he was the one who had to do reverse engineering of the formula for calculating the insurance premium.

Imagine that you're a new minister and you can't find clear information on how the insurance premium is being calculated.

Something similar was happening in price regulation. A group of students and I had to figure out how to get the data from the person who controlled it. We said to one particular student "Okay, your challenge is you have to talk to this person and somehow you have to figure out what he has been doing, and you have to make that transparent for everyone – for us, but also for the pharmaceutical companies that, right now, don't know how we are calculating the prices. The graduate student was successful. He got the data and then built a very simple macro in Excel, and constructed what we call now the La Ficha

And very simply, not at all high science – it's not physics – this is where we do the calculus of the price, and we referenced every price to international pricing. And so, it was completely transparent for the regulated companies, so that they could basically see the form and look for the price, and see if it was included correctly.

LaForge: So, it's Excel.

Andía: *Exactly, it's Excel. Before, it was like a very complicated thing, but it was completely non-transparent. So, this is very basic.*

The program uses several prices, from several countries, and an explicit formula to calculate the price we will pay. Companies charge a range of prices for the same drug. We look at the 25% cut point in the distribution. That is, not the lowest price, but the 25th from the bottom--the percentile 25 that is basically what we pick for the price.

And that was a challenge. I remember we actually loved that moment, because we were four young economists. I was the leader of the team, and we would spend 12 hours or more working on, first of all, how they did the first calculus that they did, because everything was non-transparent.

So the challenge with pharmaceutical data is that there are a lot of different measures. Some things come in milligrams, some others in micrograms, some others in milliliters – so you need boxes, pharmaceutical forms – everything – to do a proper calculation. You need to standardize all that, and for that you need a pharmaceutical chemist who can understand everything. But even then, you have a lot of doubt of whether you are comparing things that are the same, or you are, maybe, comparing things that are not the same.

So, we spent a lot of time figuring out how, from an economics point of view--from a market point of view--these things were actually

comparable, or were we comparing pears with apples. And so, that was the other challenge.

So, there was the data, the access to the data, the standardization, and then, the handling of the data was a huge challenge.

LaForge: How many drugs are we talking about in each phase of the implementation?

Andía: It varied, but more or less we analyzed 500 in each phase, although the number of pharmaceuticals that ended up being regulated was far less. At the end, in total, we regulated 1800 drugs, which is great. But we analyzed many more. Some were not regulated because there was competition in those markets, or because the price was low enough compared to international pricing. Those are the main two reasons why we regulated some.

LaForge: So, this was over how many implementation phases?

Andía: Six, with the most recent ones. But there were two years in which nothing happened. And that's the other challenge I would say. We had to figure out how to do something that was not so easy technically. We learned how to do it, then figured out a way to manage everything. Coordination, for example. We had this thing that we called a crosscheck. Nobody could just deliver their work without someone else running the same processes blindly so that to see whether they got the same results.

There were economists who had never seen a pharmaceutical name in their lives before, so, they had to learn what an "active principle" is and many things like that. In any case, we developed all that technical capacity. And then, for any reason, if you lose people, you lose the whole thing. It's not something that you can easily teach to someone else.

Andía: And then, I had to go back to finish my Ph.D. and Claudia went back to La Nacional, and Carolina had to leave. So in late 2015, the work stopped until 2017.

So, the challenges associated with this effort included getting the data, developing the human resources or capacity—and then I would add two institutional challenges. One is bureaucracy, like the old civil service. One of the arguments I made in the dissertation is that people who are able to innovate within the policymaking in some areas, I mean in Latin American countries, sometimes benefit from

being visitors, because they don't share in the usual fears. What you see in the civil service is terrible – everything is a risk. We would try to involve the civil servants, but they would always say, "This is not included in my list of functions." Not really. "Okay. So, you cannot help us?" "No."

So we ended up creating something that literature calls "pockets of efficiency." It was like a small pocket, with two university professors, a lawyer who didn't come from this background, a bunch of students and a supportive minister. Those were the people who actually ran the whole show. And it's basically because, within the bureaucracy, it's very hard to think – first, to have the ideas, but also then to implement with the risks that they entail. And those are risks like supervision, on one level, but then the other level is political. You don't want to be so visible, you don't want to be appearing in the newspapers as the evil one that is basically ruining Pfizer. You don't want to be that person because you're trying to keep your job.

LaForge: No risks.

Andía: *Exactly. So, my argument is that these new people, first of all, have some ideas about what needs to be done, but then they have the boldness, because they don't want to keep the job, they have the boldness to risk and try to do it. And they also have, in general, some peers in the community that they want to deliver to. So, if you're like me, my biggest person in the community was my dad, who was like the worst critic of what we were trying to do. But he reminded me constantly: "You want to deliver to the people who you care about." So, in my case, it was my dad, but also the academic community. I thought, "Okay, there are some colleagues that are expecting that I do a great job."*

In general, I think it is far more likely that these kinds of people innovate and that they pull it through, even if they have to work extra hours, they are willing to risk everything – their marriages and all. And those are things that a normal bureaucrat would not do.

LaForge: Wait, why was your dad opposed to it?

Andía: *He's also striving for what should be the perfect regulation, but then we had to do what is possible within our very many limitations: not just the bureaucratic inertia but also external political challenges.*

The influence of the pharmaceutical industry was felt in several ways, through international pressure, the media, the Ministry of Commerce,

of Trade, the presidency. These are people that can meet in the sauna of the club with someone – and if you're not going to that sauna, you're completely out of it. But that happens, and there can be pressure from several flanks and you're trying to figure out how to manage.

So, going back to my dad, I think he didn't care if we faced these restrictions. We should just strive for the best possible outcome. And we're like, "Okay, yes that's the direction, but we are here trying to convince people who are difficult to convince, and – yeah, giving up some things, so that we can get something else. So, it will determine if we enter that type of negotiation.

The other thing that happens when you see highly motivated people doing something for deeper reasons than just the pay is that it gets people excited. My best example for that is Aura Maria, who was the representative of the presidency in the whole regulatory process. She was very skeptical of everything. She's like an orthodox lawyer – and an orthodox economist. She loves the private sector. She didn't want us to mess with the pharmaceutical industry, especially at the beginning. But she became an advocate. She ended up being a huge help because she was like a broker between us and the industry, and a broker between us and the more conservative Ministry of Trade and the presidency. So, she was key to the whole process.

And I think Aura Maria got involved and became excited because it was nice to work with us – there was an energy and it felt like something was happening. Sometimes it's hard to find motivated people who realize it's possible to do great things. Normally, it takes ten years to slightly change.

LaForge: Can you explain the OECD accession fight and how that played out here?

Andía: *We always had international opposition to everything. We always received a letter from some embassy complaining about something. So we would hear "This upsets our investors," or, "This is not exactly aligned with the free trade agreement with the U.S.," that type of argument. Or, "This would not help foreign investment," and all that.*

But the OECD was a different discussion. I still don't know why, but the president was completely obsessed with getting into the OECD. It was not a possibility to not get into the OECD. At about that time we began working on the national plan.

LaForge: The 2014 plan?

Andía: *Yes. We included several articles in the plan—an article about the value-based pricing, an article about having some kind of control by the Ministry of Health of patents issued in pharmaceuticals, and an article about centralized negotiations.*

LaForge: So those three are important priorities for a minister.

Andía: *Yes, exactly. And we included those articles despite a lot of opposition. I remember, especially, the meetings with France, Swiss, and U.S. embassies at the same time – all aligned. They hated all those articles. At the end, we met with the U.S. commercial representative at the embassy. I understand in the U.S. they don't regulate any price; they have the highest prices in the world. I understand. But that France is telling us that we cannot do something that they do, is awful. And the French representative was like, "Yes, but we do it differently." We were not saying how we were going to do it. We were saying, "We are going to do this."*

So, we had all those meetings and there was also a lot of lobbying in Congress, but at the end, everything passed. Which, to be honest, I didn't think would happen, because I thought the pharmaceutical companies' lobby in Congress would be far more successful. We weren't able to go and defend our articles because they had four delegates from the Ministry of Health to defend everything. But of the people who went, one was a very close friend. The congressmen were basically saying, "in this context, at this moment, the pharmaceutical industry has the worse reputation," because when the old scandals of how they were charging us twice, three times, sometimes four times what they charge elsewhere came to the media, they lost any leverage.

It *was very politically unwise to back the pharmaceutical companies; it was something that you cannot do. If you ask pharmaceutical companies, they'll tell you that they have ever since been trying to do something to recover their reputations, because for now, many people just think they're thieves. Yes, they can do innovation, but they're thieves. And so, I think that played a big role in why it passed in Congress.*

LaForge: A quick aside, a technical question. When they passed the health package in Congress, did they go item by item, or did they pass it whole as a package? Like, "Here's the health package. Vote it yes or no."

Andía: *They go article by article*.

Well, if they don't have any questions, they can pass as a whole package.

It became, I think, the number one priority of the pharmaceutical industry, to fight back on value-based pricing. They were less concerned about patents because they knew that the patent office was completely aligned with them then, so nothing could happen, really. So, the issue that they were very concerned with was value-based pricing, and especially that value-based pricing was linked or partnered with the marketing registration, marketing approval. So, basically, it suggested that if they didn't get a price then they couldn't market the product. They hated that, although Brazil does it exactly like that, but we cannot do it.

And so it became a high priority. They talked about it everywhere. We had to consult with the WTO (World Trade Organization), and through the WTO came the comments of the Swiss and the U.S. governments, saying exactly what they said the in meetings. France stopped bothering us. It was only Switzerland and the U.S. And then, when that didn't work, I think that's when they came up with the OECD (Organization for Economic Cooperation and Development) as a great place to bring pressure.

...

LaForge: So, they caved to the OECD – the president did, basically, because he really wanted OECD accession.

Andía: *He didn't get involved in the details, he just said, "Do whatever you need to, so that we can get access to this." [A close staff member and the Colombian representative to the OECD] got involved. Both of them really are friends with the minister, Alejandro Gaviria, and they respect him, so they told him, "Well, we need to fix this. Let's give them something so that they can agree."*

USAID pressured us a lot at first, and then apparently even USAID got tired of pharma, said, "Okay, this is what they said, do some of that, so that we can say, 'Yes, we got this word for you.'"

And that's how it happened, but it was also because we had already issued a decree, we had to amend it just to please pharma –and then place it on public consultation for only one day, even if they're breaking mostly OECD rules that say that you have to give at least

15 days of public consultation for every norm. And at the end – well, they were kind of happy, and so there was a huge division within pharma. The director of the association of pharmaceutical companies was happy with it.

LaForge: AFIDRO (Association of R&D Pharmaceutical Manufacturers) right?

Andía: *AFIDRO, yes. So, the director said, "I'm happy with this. This is exactly what we asked for, that they de-link the marketing approval from the price." But then, all the companies thought that was unsatisfactory, it wasn't exactly what they asked – basically, we needed to eliminate everything so they could be happy. And so, there was this division within the private sector. ... We got the accession from the OECD. And at the very last minute, we had everything ready. But at that very last minute we were sunk, because we lacked a certification that the superintendents of commerce and trade needed to give us--that any regulation that affects any market needs to have—to attest that a practice does not limit competition.*

LaForge: Approval?

Andía: *Generally they provided this kind of certification in two days, but this time, suspiciously, the review took a month. Well, that's it. It didn't happen. So, the whole OECD drama ended up in having a decree that probably nobody is going to implement, because this government doesn't seem inclined to deepen pharmaceutical regulation.*

...So, you have a $10 billion deficit, you want to improve conditions in public hospitals, and you want to pay for expensive pharmaceuticals. There's no way you can do all of those things – and you want to respect the autonomy, the judgment of the doctors. For me, there's no way all these things can happen at the same time. You need to cut somewhere. Maybe pharmaceuticals are not the only thing, I agree with that, but you have to do something to reduce costs. At the prices that those drugs are commanding, even one can put everything into jeopardy.

LaForge: Where does the system break, as you see it, because this seems like a very unsustainable path that you have to provide everything for everyone by traditional ruling. Yet, you're trying, also, to improve quality and expand access at the same time.

... *End of pricing discussion in this interview.*