Concepción Campa Huergo, PhD (h.c.)

President & General Director Finlay Institute

By Conner Gorry

Pharmacist, biochemist, and lead scientist of the Cuban team that developed the meningitis B vaccine, Concepción Campa has been internationally recognized for her scientific contributions to children's health; this vaccine, patented as VA-MENGOC-BC®, was awarded the World Intellectual Property Organization's Gold Medal in 1989.

Currently, Campa is President and General Director of the Finlay Institute, the Cuban scientific center dedicated to research, development, production, and marketing of vaccines for human use. Among many other distinctions, Concepción Campa is: Senior Member of the Cuban Academy of Sciences; World Health Organization Temporary Consultant & Scientific Advisor; Pan American Health Organization Temporary Advisor; Member of the Scientific Council of the Cuban Ministry of Public Health; and Member of the Cuban Expert Committee on Vaccines. She received an honorary PhD from the University of Havana in 1996.

Dr Campa sat down with **MEDICC Review** to discuss Cuba's vaccine research approach, development of the meningitis B vaccine, what it's like to lead an internationally-renowned scientific institution, and more.

MEDICC Review (MR): As part of the Scientific Pole, the Finlay Institute has contributed to the development of many vaccines, especially those aimed at so-called "diseases of the poor." What vaccines has the Scientific Pole produced and what is currently on the drawing board?

Concepción Campa (CC): First, let me say that Cuba has a research approach that doesn't only take into account Cuban population health, but also global population health, especially the poor of the world – those that need medicine and preventive vaccines most.

The Vaccine Program is one of the Scientific Pole's most aggressive, and many vaccines have been developed here in recent years – the cholera vaccine candidate for instance, which is designed explicitly for poor countries, not tourists. Every year, thousands of people around the world die from this preventable disease. [For more on the Cuban cholera vaccine candidate see Cuba Health Reports, www.medicc.org/publications/cuba_health_reports/020.php, Eds].

The Finlay Institute worked diligently with several other scientific centers for four years on this vaccine candidate. And this type of collaboration, between many scientific centers, is one of the beauties of Cuban biotechnology. Almost all research happens this way, with two, three, four, or more centers collaborating together. In the case of the cholera candidate; the



Finlay Institute, Pedro Kourí Institute of Tropical Medicine, and National Center for Scientific Research [IPK and CNIC respectively according to their acronyms in Spanish, Eds.] are all working together.

Our leptospirosis vaccine is another example. A vaccine exists, but is rarely available commercially because leptospirosis – a disease transmitted by rodents – is a disease of the poor and so it's not profitable for multinational drug companies. There-

fore, the Cuban vaccine is an alternative that is applicable, particularly in Latin America.

The meningitis B vaccine is another Cuban biotech product in which the Finlay Institute figured largely. At the moment this is the only effective vaccine against the disease available internationally. This is a different story however, because meningitis B is not a disease that discriminates: it affects the poor as well as the rich. It's very satisfying for us to produce vaccines for these children, wherever they are in the world.

MR: You led the team that developed VA-MENGOC-BC® 20 years ago. I understand that you and other scientists that worked on the vaccine, as well as your children, served as the first vaccination volunteers. What was that like?

CC: This is interesting because in Cuba there has been a centuries-long tradition of scientists being the first to test their vaccines – with Carlos Finlay and Tomás Romay for instance – so we weren't breaking new ground there. Our team was conscious of the fact that what we were doing carried risks because we had to work with live germs and meningococcal disease can be transmitted by asymptomatic carriers to others, but this was trumped by the risks faced by all the Cuban children who might be exposed to the disease. At that time, there was an epidemic, with an extremely high incidence rate among children younger than six: more than 160 per 100,000 and almost every day Cuban children were dying from type B

meningitis. The parents' pain, distress, and fear were truly great.

Once we had the vaccine and concluded pre-clinical trials in lab animals and were scientifically certain that it was a safe vaccine, we then had to *demonstrate* that it was safe and effective in humans. (See: *Cuban Meningococcal BC Vaccine: Experiences and Contributions from 20 Years of Application*). So the researchers who discovered and developed the vaccine were the first to receive it. When the time came to vaccinate children, ours were the first. We explained that the vaccine was the one their moms and dads had worked on and would protect them from the disease.

MR: In many countries, including the United States, children of all ages die from meningitis B. What countries have been using the Cuban vaccine? Is it sold, donated or traded?

CC: The Cuban meningitis vaccine is most widely used in Latin America, where more than 55 million doses have been administered. The vaccine has been donated to countries in Africa, to Uruguay when there was an outbreak there, and is used in vaccination campaigns in Brazil, Colombia, and other countries.

Regarding vaccine sales, we generally take into account where a vaccine will be administered. It's not the same to sell a vaccine to the private sector, where they charge an arm and a leg, as to a public health system for vaccination campaigns or when there's an epidemic. Since the 1980s, Cuba has also developed a different approach, primarily with the Global South, based on joint vaccine production and technology transfer. This helps control costs related to production and shipping and allows the recipient country to administer their own quality control measures. We have this type of agreement with Brazil, Iran, India, China, Vietnam, and others. This is very rewarding for us because our end is not profit, but rather helping other countries help their own populations, with their own ingenuity.

MR: In the United States, there's a process overseen by the Food & Drug Administration (FDA) that monitors the different stages of vaccine research, pharmaceutical development, and the like. Does Cuba have a similar process?

CC: Of course. Our vaccine research and development process follows all internationally-established protocols. Not only those of the FDA, but also those of the European Union and Good Manufacturing Practices (GMPs) for clinical trials, which have to be rigorously applied.

In the case of the meningococcal vaccine specifically, the clinical trials were designed by the Ministry of Public Health and the Finlay Institute, in collaboration with the Centers for Disease Control (CDC) in Atlanta. Those trials were completed successfully, within recognized guidelines, as are all new Cuban vaccines, like the one against *Haemophilus influenzae* type b, hepatitis B, and others within the National Immunization Program. (See Policy & Practice: *Cuba's National Immunization Program*).

MR: Can you explain that program?

CC: The children's vaccination program is one of our most comprehensive. All Cuban children are vaccinated free of charge against 13 diseases, so that our national vaccination rate is more than 95% against meningitis B and C, hepatitis B, diphtheria, tetanus, pertussis (whooping cough), measles, mumps, rubella, typhoid fever, tuberculosis, polio, and *Haemophilus influenzae* type b (See Interview: *Dr Vicente Vérez Bencomo*).

MR: The World Health Organization (WHO) has given its seal of approval to the Cuban hepatitis B vaccine for immunization packages provided by UN organizations like UNICEF. What does that mean?

CC: WHO approves vaccines for purchase by international authorities to carry out massive immunization campaigns in the Third World. Getting approved by WHO is a long, complex, and costly process that we succeeded in doing with the hepatitis B vaccine. [The Cuban *Haemophilus influenzae* type b (Hib) vaccine, produced by the Center for Genetic Engineering and Biotechnology, is also undergoing WHO evaluation for inclusion in international vaccination packages, Eds.]

MR: Do you think Cuban scientists identify with people from other developing countries?

CC: Absolutely. Cubans in general have a very special connection with other countries because wherever there's pain it's our pain, where there's suffering, a mother crying or a child dying, that affects us. It doesn't matter where, north or south. The difference is that developing countries have fewer possibilities for easing that pain or saving that child. As a small, poor country, we identify with that.

I've been witness to this at the Finlay Institute when we learn a vaccine is destined for an African country where children are dying, or a Latin American country where people need it. The enthusiasm and motivation with which everyone works is incredible – all night, weekends: It's really impressive.

MR: People might be surprised to learn that more than half of all health professionals in Cuba are women and that Cuban women direct a lot of the scientific research. Has it been a difficult process for you?

CC: It has been difficult in the sense that is very tough to break from cultural mores, like women are limited and can't do what men do, for instance, which is ingrained, even in Cuba. But we have things working in our favor too, like legislation that protects us, guaranteeing equal opportunity to study and work. I have no problem whatsoever putting a woman in charge of a large, important project because they've shown they can produce and succeed just like a man.

MR: Can you speak about the US embargo and how it affects biotech development here?

CC: Sometimes less, sometimes more, but the embargo has always had an impact on the development of medicines and vaccines in Cuba. For example, at times it has been impossi-

ble to buy the raw materials to produce pharmaceuticals or replacement parts for high tech equipment. Likewise, we've had to travel the world looking for equipment and all the shipping problems and higher costs that implies. Cold chain-dependent products are especially sensitive in this regard. Scientific literature and exchange are further casualties — there are scientists with whom we would love to work and share and compare results, but we can't due to US restrictions. I think science would benefit enormously if US and Cuban scientists could collaborate, attend, and host conferences together.

MR: How about when it comes to vaccine distribution? Has the embargo had any effect on that?

CC: Yes, most definitely. In the United States, for example, there are people getting ill with type B meningitis and the Cuban vaccine, the only commercially available vaccine, is not available to them [the US embargo of Cuba also prevents US

authorities and doctors from buying Cuban biotechnology products, Eds.] The embargo affects many Cuban products in that it impedes, slows down, and essentially makes it impossible to distribute to some countries that need them, including the United States.

What's worse than the embargo though, what really saddens us and hits us in the heart is the totally unjust accusation of bioterrorism. [The US backpedaled from this allegation, made in 2002 by then Under Secretary of State for Arms Control and International Security, John Bolton, when intelligence reports failed to find conclusive evidence supporting it. See Adherence to and Compliance with Arms Control, Nonproliferation, and Disarmament Agreements and Commitments, Bureau of Verification & Compliance, US State Department, Aug 30, 2005, Eds.] Here we are working tirelessly day and night to save lives. It's inconceivable that these same people would want to take lives.

