

Big Pharma and the Gates Foundation: “Guinea Pigs for the Drugmakers”

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Despite annual revenues approaching \$1 trillion, the global pharmaceutical industry has lately experienced a critical decline in the rate of profit, for which it lays most of the blame on regulatory requirements. A US think tank has estimated the cost of new drug development at \$5.8 billion per drug, of which 90 per cent is incurred in Phase III clinical trials mandated by the US Food and Drug Administration and similar agencies in Europe.⁴¹ (These are tests administered to large groups of human subjects in order to confirm the effectiveness and monitor the side effects of new vaccines and other medicines.) The international business consulting firm McKinsey & Company called the situation “dramatic” and urged Big Pharma executives to “envision responses that go well beyond simply tinkering with the cost base” – primarily the relocation of clinical trials to emerging markets, where drug safety testing is seen as relatively cheap, speedy, and lax.⁴²

It is in this specific context that BMGF’s intervention in the distribution of certain vaccines and contraceptives must be seen. Heavily invested in Big Pharma,⁴³ the Gates Foundation is well positioned to facilitate pharmaceutical R&D strategies tailored to the realities of the developing world, where “[t]o speed the translation of scientific discovery into implementable solutions, we seek better ways to evaluate and refine potential interventions—such as vaccine candidates—before they enter costly and time-consuming clinical trials.”⁴⁴ In plain language, BMGF promises to assist Big Pharma in its efforts to circumvent Western regulatory regimes by sponsoring cut-rate drug trials in the periphery.

The instruments of this assistance are Gates foundation funded institutions like the GAVI Alliance, the Global Health Innovative Technology Fund, and the Program for Appropriate Technology in Health (PATH) – public-private partnerships purportedly devoted to saving Third World lives. Notionally independent but so heavily funded by Gates as to function as virtual arms of the Foundation, these organizations began to conduct large-scale clinical trials in Africa and South Asia in the mid-2000s.⁴⁵

Africa soon experienced an “unprecedented increase in health research involving humans” who were typically “poverty-stricken and poorly educated”⁴⁶; the results were predictably lethal. In 2010 the Gates Foundation funded a Phase III trial of a malaria vaccine developed by GlaxoSmithKline (GSK), administering the experimental treatment to thousands of infants across seven African countries. Eager to secure the WHO approval necessary to license the vaccine for global distribution, GSK and BMGF declared the trials a smashing success, and the popular press uncritically reproduced the publicity.⁴⁷ Few bothered to look closely at the

study's fine print, which revealed that the trials resulted in 151 deaths and caused "serious adverse effects" (e.g., paralysis, seizures, febrile convulsions) in 1048 of 5949 children aged 5-17 months.⁴⁸ Similar stories emerged in the wake of the Gates-funded MenAfriVac campaign in Chad, where unconfirmed reports alleged that 50 of 500 children forcibly vaccinated for meningitis later developed paralysis.⁴⁹ Citing additional abuses, a South African newspaper declared: "We are guinea pigs for the drugmakers."⁵⁰

It was in India, however, that the implications of BMGF's collaboration with Big Pharma first rose to widespread public attention. In 2010 seven adolescent tribal girls in Gujarat and Andhra Pradesh died after receiving injections of HPV (Human Papilloma Virus) vaccines as part of a large-scale "demonstrational study" funded by the Gates Foundation and administered by PATH.⁵¹ The vaccines, developed by GSK and Merck, were given to approximately 23,000 girls between 10 and 14 years of age, ostensibly to guard against cervical cancers they might develop in old age.

Extrapolating from trial data, Indian physicians later estimated that at least 1,200 girls experienced severe side effects or developed auto-immune disorders as a result of the injections.⁵² No follow-up examinations or medical care were offered to the victims. Further investigations revealed pervasive violations of ethical norms: vulnerable village girls were virtually press-ganged into the trials, their parents bullied into signing consent forms they could not read by PATH representatives who made false claims about the safety and efficacy of the drugs. In many cases signatures were simply forged.⁵³

An Indian Parliamentary Committee determined that the Gates-funded vaccine campaign was in fact a large-scale clinical trial conducted on behalf of the pharmaceutical firms and disguised as an "observational study" in order to outflank statutory requirements.⁵⁴ The Committee found that PATH had "violated all laws and regulations laid down for clinical trials by the government" in a "clear-cut violation of human rights and a case of child abuse."⁵⁵ The Gates Foundation did not trouble to respond to the findings but issued an annual letter calling for still more health-related R&D in poor countries and reaffirming its belief in "the value of every human life."⁵⁶

Making markets

By thrusting the HPV vaccine on India, The Gates Foundation was not merely facilitating low-cost clinical trials but was also assisting in the creation of new markets for a dubious and underperforming product. Merck's version of the vaccine, called Gardasil, was introduced in 2006 in conjunction with a high-powered marketing campaign that generated \$1.5 billion in annual sales⁵⁷; the vaccine was named "brand of the year" by *Pharmaceutical Executive* for "building a market out of thin air."⁵⁸ Aided by enthusiastic endorsements from the medical establishment, Merck at first persuaded Americans that Gardasil could protect their daughters from cervical cancer. In fact the vaccine was of questionable efficacy:

The relationship between [HPV] infection at a young age and development of cancer 20 to 40 years later is not known. ... The virus does not appear to be very harmful because almost all HPV infections are cleared by the immune system. [S]ome women may develop precancerous cervical lesions and

eventually cervical cancer. It is currently impossible to predict in which women this will occur and why.⁵⁹

The prestigious *Journal of the American Medical Association* in 2009 openly questioned whether the vaccine's risks outweighed the potential benefits.⁶⁰ As word of Gardasil's defects emerged, American and European women began to decline the vaccine, and by 2010 Fortune Magazine declared Gardasil a "marketplace dud" as year-over-year sales fell by 18 percent.⁶¹ GSK's copycat HPV vaccine, Cervarix, experienced a comparable sales trough.

Billions in profits and capitalization were at stake. At this stage the Gates Foundation stepped in. Its principal tool was the GAVI Alliance, launched by BMGF in 2000 with the "explicit goal to shape vaccine markets."⁶² GAVI was charged with co-financing vaccine purchases with Third World public health ministries, meanwhile "finding the type of large-scale funding needed to sustain long-term immunisation programmes" and "laying the foundations that will allow governments to continue immunisation programmes long after GAVI support ends."⁶³ In essence, BMGF would buy up stockpiled drugs that had failed to create sufficient demand in the West, press them on the periphery at a discount, and lock in long-term purchase agreements with Third World governments.

In 2011 GAVI held a highly publicized board meeting in Dhaka where, with the enthusiastic endorsement of UN Secretary General Ban ki-Moon, it announced a worldwide campaign to introduce HPV vaccines to developing countries: "If [developing] countries can demonstrate their ability to deliver the vaccines, up to two million women and girls in nine countries could be protected from cervical cancer by 2015."⁶⁴ GSK adopted a "Global Vaccine Availability Model" involving tiered pricing to permit "transition[ing] into poorer countries with the help of 'partners' such as UNICEF, the World Health Organization, and the Global Alliance for Vaccines and Immunization."⁶⁵ Meanwhile PATH was rushing to complete a large-scale, five-year long project "to generate and disseminate evidence for informed public sector introduction of HPV vaccines" in India, Uganda, Peru and Vietnam. An Indian Parliamentary report observed: "all these countries have state-funded national vaccine immunization programs, which if expanded to include Gardasil, would mean tremendous financial benefit to the ... manufacturer."⁶⁶

By FYE 2012, Merck was able to report a 35 percent jump in worldwide Gardasil sales, reflecting *inter alia* "favorable performance in Japan and the emerging markets," where "sales growth is being driven by vaccines."⁶⁷ Evidently, a drug rightly deemed suspect by Americans would be good enough for women in the developing world.

Other dangerous drugs that failed to gain a toehold in Western markets have received similar attention from the Gates Foundation. Norplant, a subcutaneous contraceptive implant that effectively sterilizes women for as long as five years, was pulled from the US market after 36,000 women filed suit over severe side effects undisclosed by the manufacturer, including excessive menstrual bleeding, headaches, nausea, dizziness and depression.⁶⁸ Slightly modified and rebranded as Jadelle, the same drug is now being heavily promoted in Africa by USAID, the Gates Foundation, and its affiliates. A recent article on the Gates-sponsored website *Impatient Optimists* elides its dangers and disingenuously states

that the drug “never gained traction” in the US because inserting and removing the device was “cumbersome.” With Gates Foundation support, however, Jadelle “has played a pivotal role in bringing implants to the developing world” and is soon to be complemented by a second Norplant clone, Merck’s Implanon.⁶⁹

An equally risky contraceptive, Pfizer’s Depo-Provera, recently received the Gates Foundation imprimatur for distribution to poor women worldwide. In the US and India feminists fought against approval of the injectable drug for decades due to its alarming list of side effects, including “infertility, irregular bleeding, decreased libido, depression, high blood pressure, excessive weight gain, breast tenderness, vaginal infections, hair loss, stomach pains, blurred vision, joint pain, growth of facial hair, acne, cramps, diarrhea, skin rash, tiredness, and swelling of limbs”⁷⁰ as well as potentially irreversible osteoporosis.⁷¹

After the US Food and Drug Administration succumbed to industry pressure and granted approval in 1992, studies found a marked racial disparity in Depo-Provera prescriptions between white and African American women, leading to charges that “this form of long-acting provider-controlled birth control is routinely given to women of color in order to deny them the ability to control their own reproduction.”⁷² White American and European women, by contrast, receive the drug only rarely and typically as a treatment for endometriosis, greatly limiting its commercial potential in the West.

Hence Pfizer stands to benefit enormously from a Gates-sponsored program, announced with much fanfare at the 2012 London Summit on Family Planning, to distribute the drug to millions of women in South Asia and sub-Saharan Africa by 2016:⁷³

[Y]ou do the numbers: If 120 million new women users chose Depo-Provera, at an estimated average cost between \$120-\$300 per woman annually, that works out to \$15 billion to \$36 billion in new sales annually, a nice payoff from leveraging \$4 billion in research money.⁷⁴

Foundation publicity suggests that its aggressive backing of a discredited drug is merely a response to appeals from poor women. “Many [African] women want to use injectable contraceptives but simply cannot get access to them,” claimed PATH President and CEO Steve Davis.⁷⁵ Reproductive rights activist Kwame Fasu disagrees: “No African woman would agree to being injected if she had full knowledge of the contraceptives’ dangerous side effects.”⁷⁶

Notes

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44. Discovery and Translational Sciences Strategy Overview, BMGF website, <http://www.gatesfoundation.org/What-We-Do/Global-Health/Discovery-and-Translational-Sciences>. ([back](#))

45. Gates-funded public-private consortia typically subcontract with local Contract Research Organizations (CROs) to conduct trials in the field, allowing the Foundation to maintain arms-length distance from the realities of recruiting and injecting human subjects, which frequently involves deception and coercion. The global CRO industry is projected to reach over \$32 billion by 2015. See WEMOS, *The Clinical Trials Industry in South Africa: Ethics, Rules and Realities*, July 2012, pp. 11-13, http://www.wemos.nl/files/Documenten%20Informatief/Bestanden%20voor%20'Medicijnen'/Clinical_Trials_Industry_South_Africa_2013_v3.pdf. ([back](#))

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