Editorial

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Drug & device development for infants and children in 2014; is it enough? what do you really think?

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Alan H Cohen
Department of Pediatric Pulmonology, Stanford University School of Medicine, USA

Correspondence: Alan H Cohen, Department of Pediatric Pulmonology, Stanford University School of Medicine, 291 Campus Dr, Stanford, CA 94305, USA, Tel 805-341-5333, Email alanhcohen@eddingpharm.com

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Editorial

Having the unusual career path of being a board certified pediatric pulmonologist that teaches and still sees patients at an Academic Children's Hospital in Northern California, while employed fulltime in the bio/pharma-drug development space I have the ability to understand from firsthand experience about the challenges and costs of drug discovery and the complexities of medication costs. I am also increasingly impressed, yet disappointed at the lack of innovation and creative drug discovery that is directed to benefit children specifically,…and not just adults.

It wasn't that many years ago that I inquired about drugs studied and approved for use specifically in infants and children, and even as recently as the early 1990's that number was disappointingly small and about 40-50, while there were thousands of drugs already safely available for adults. The same is true for device development in children. The risks are often high, the potential financial benefits low, and more often than not we pediatricians are left with little to no data, no proper working models and only our ingenuity and an unmet need to fuel our actions in the clinic and hospital setting. This is not how it should be done, we all know this – yet we continue to allow it by acceptance of the "ways things are and have always been".

Legislation since the early 1990's has helped to incentivize for-profit companies developing potential treatments to be sure to include pediatric drug development within their planning, but it isn't always clear that those post approval commitments, and the small elongation of patent protection with successful completion of those pediatric studies is incentive enough to gain the central focus and financial support needed to bring more safe and effective novel therapies to children worldwide. In fact, although there are now more than 100 approved pediatric drugs in the USA, many of the newly added treatments are only serving a very discrete and small group of patients – often under the auspices of "orphan drug" development, which has proven to be a desirable area to work given the generous remuneration often associated with rarer diseases and smaller numbers of patients to a given health plan or state. Orphan drugs can often demand many hundreds of thousands of dollars per treatment and if children happen to be the age group targeted, we can chalk one more drug up for kids, albeit small numbers – but oftentimes for life-limiting inborn errors of metabolism or genetic defects.

I, as well as many of my colleagues in both the academic and private sector would like to see pediatric drug and device development treated as importantly and centrally as that for adults, however with a population that doesn't participate in the election process and that doesn't pay taxes at a federal, state or local level it sadly isn't a priority for anyone but the children who typically are marginalized, and the few people who should be advocating for them…such as healthcare professionals, like us. That said, I would ask each of you if you are satisfied with the treatment choices you have for the majority of the children you care for and serve and if you find yourself answering no, or being envious of all of the choices your Internal Medicine or Family Practice colleagues have at their disposal – you have answered the question,...as no. If that is the case we need to better advocate for our patients. You can do that by more strongly supporting the regular use of therapies already approved for children, and making your opinions clear to government officials, drug and device development companies and our specialty membership organizations – that are already advocating for children.

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