



APPENDIX D:

THE PEDIATRIC RULE IS CONSTITUTIONALLY DEFICIENT BECAUSE IT PURPORTS TO AUTHORIZE "TAKINGS" OF PRIVATE PROPERTY FOR PUBLIC USE WITHOUT JUST COMPENSATION.

A key purpose of the Takings Clause of the Fifth Amendment to the United States Constitution is "to bar Government from forcing some people alone to bear public burdens which, in all fairness, should be borne by the public as a whole." Armstrong v. United States, 364 U.S. 40, 49 (1960). Yet that is precisely what the Pediatric Rule seeks to do – impose on pharmaceutical manufacturers the burden of discovering new uses for certain chemical compounds even if they have no desire to market those drugs for those uses. The taking is particularly obvious with respect to drugs that are already on the market. With respect to such drugs, FDA is asserting the authority to command **manufacturers to reformulate the drug and spend what could be massive amounts of research funds to assess whether the drug is safe and effective in pediatric populations.** What is more, FDA claims this power even if the manufacturer **has** disclaimed any pediatric use. **This** is hardly different from the government commanding one private citizen, **as** a condition of driving to work on a particular road, to erect warning **signs** on that road for all to see.

The taking is no less egregious with respect to **drugs** that are not yet on the market. **FDA** approval is not the conferral of a public benefit. It is **an** approval that one must secure before using one's **own** property. **FDA** may not condition its approval of that property right on the dedication **to** the public of potentially massive resources **in the form of research into the** potentially foreseeable pediatric uses of the product. The government can **no** more impose such a condition on its approval than a **land-use commission can condition an** approval to build a new

factory on the builder's simultaneous financing of a local school. See Nollan v. California Coastal Comm'n, 483 U.S. 825, 837 (1987) (characterizing an attempt to achieve a public easement as a condition of approving a land use as "an out-and-out plan of extortion" (internal quotations and citation omitted)).

Here, as in Dolan v. City of Tigard, 512 U.S. 374, 388 (1994), "the degree of the exactions" demanded by **FDA's** conditions do not bear the "required relationship to the projected impact" of the manufacturer's proposal to sell these drugs. The government may not require manufacturers to **undertake massive research for the public's benefit or use when they** themselves do not intend to benefit by such use, and when they manifest that intention by not claiming such a use. Essentially, the government **is using the drug manufacturer's** marketing of the drug or request for approval of a new drug **as an** excuse for taking property simply because at that particular moment" the government is being **asked** for **an** approval. Id. at 390. Put simply, **FDA** may not require the manufacturers to dedicate private property – i.e., their research funds and facilities – for some future public use **as** a condition either of continuing to market the drug or of obtaining approval to market **the drug** for a different purpose.¹

¹ The Supreme **Court** has **made clear that** "simply denominating a government measure as a 'business regulation' does not **immunize it from** constitutional challenge on the ground that it violates a provision of the Bill of **Rights.**" Dolan, 512 U.S. at 392.