Protecting the Autonomy of Industry Regulators

What is the issue?

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- Chairman of the “National Pharmaceutical Pricing Authority” (NPPA), Mr. Bhupendra Singh was recently ousted ahead of time without a replacement.
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- There seems to lack of transparency and credibility in the appointments and removals at multiple regulatory bodies in the country.
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What creates suspicion?

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- **NPPA -** NPPA is the pricing regulator for medicines and medical devices in the country and works under the Union Ministry of Chemical and Fertilizers.
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- Mr. Bhupendra was moved out ahead of time, after a little over two years at the helm of NPPA even before identifying a replacement.
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- Notably, his predecessor Mr. Injeti Srinivas was also transferred out in less than a year of assuming office.
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- These episodes are particularly uncomforting because there seems to be a possible industry pressure in the ouster of these chairpersons.
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- Notably, both these people had taken critical action on drugs and medical devices manufacturers and established price controls for medical implants.
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- These were actually laudable efforts to bust inflated distribution margins (up to 1000% plus in some cases) on cardiac stents and other consumables.
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- **DCGI -** DCGI's office is entrusted with giving approvals to drugs and other products marketed in the country and works under the Union Health Ministry.
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- Dr. GN Singh, who has had a respectable tenure as the “Drug Controller General of India” (DCGI) was recently replaced arbitrarily.
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- It is also tasked with inspecting drug manufacturing facilities across the country, besides watching over all clinical trials (both animals and humans).
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- GN Singh’s tenure saw significant action in cleaning up the clinical trials segment and the sale of fixed-dose combination medicines in the country.
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- **Others -** There were a bunch of inexplicable transfers in the health ministry, including that of “Director General of Health Services” Dr Jagdish Prasad.
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What is the way ahead?

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- **The Malice -** While one can’t prove that industry pressure caused the ouster of these people from office, there is ample scope for speculation in that regard.
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- Considering the harsh manner in which the above officers were shunted out, it gives little incentive for a new person in office to operate independently.
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- The high-headed approach of the government is likely to erode the institutional credibility of regulators, which is of serious concern.
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- **Way Forward -** Instead of muzzling the regulators, the government needs to groom probable candidates with the right scientific and administrative skills.

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- Regulators need functional autonomy, and a fixed term (say five years) to implement policies and better structure regulations
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- And if anyone is removed before their term ends, it needs to be for inefficiency or corruption and that reason needs to be made public.

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- Stakeholder involvement in policy formulations needs to be enhanced by regularly engaging - the pharma industry, health service providers and the civil society at large.
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Source: Indian Express

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