Obfuscating with transparency?

The US Environmental Protection Agency (EPA) asked for public comments on a proposed rule published on April 30, 2018, which *"provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation.* [(1)] This call for transparency extends to the Agency's own studies and dose-response models upon which reference values are calculated to support final regulatory standards

The proposed rule is an obvious and necessary step for the Agency of a democratic nation, conscious of the coercive nature and massive costs of its policies and regulations, and of its authority to impose sanctions, large fines and even detention to transgressors. This authority is constrained by the ethical and constitutional contexts of free societies, with the expectation that policies, orders and regulations are not dictatorial or irrational, but grounded on independently testable evidence, or in accord with sensible precautionary tradeoffs.

Leaked to the press before its official publication, the proposed rule encountered a surprising barrage of criticism from several sources beginning with a May 4, 2018 Science article, authored by the chief editors of Science, Nature, Cell, PLoS ONE and the Proceedings of the National Academy of Sciences.[(2)] The same issue of Science included two critical pieces by the journal's staff.[(3, 4)] On May 14, 2018 Science carried a critical editorial by the journal's editor-in-chief, [(5)] followed shortly after by a staff article in Nature.[(6)]

Most staff papers trail the line set by their editors, adding innuendo and ad hominem digressions. Of the editorials, the better rounded and specific is the one of May 14, 2018 in Science with the title "Obfuscating with transparency", authored by the editor-in-chief of the journal.[(5)] The editorial argues the proposed EPA rule would "undervalue many scientific publications and limit the impact of valuable information", meaning provisional academic work and human data under privacy protection. Balancing arguments are not offered, although privacy pretexts can also be invoked to subtract data from scrutiny, while well-conceived studies protective of privacy have been capable of offering transparent, published and effectively coded data.

However, primary raw data are not needed - the Science editorial asserts -, because "…scientists are trained in judging research publications even without access to the

underlying data", and to generate judgmental interpretations across multiple publications. The editorial effectively endorses policies based on weight of evidence judgments by "those with training in making these judgments": a regulatory position asking for the most forceful dissent on intellectual and ethical grounds.[7] After the Science editorial, the Nature staff article of May 24, 2018 decries EPA's proposed rule because "robust science is being challenged", fearing it would "exclude an enormous amount of respected evidence." The article is silent on how reports without transparently shared data could represent robust and respected science. [6]

The EPA was established in the early 70's with an exceptionally permissive statutory mandate. Sensitive to allegations of arbitrariness, the agency introduced regulatory science default assumptions claiming scientific support for policies and regulations bereft of objective science backing. Supported by panels of the National Academy of Sciences,[8] the Agency further defended its decisions by selective expert consensus and not from verified data.[7] In this light, EPA's new proposal to restrict justifications of its actions to studies offering transparent public data is commendable, although this attribute alone hardly qualifies a majority of such studies for the assessment of human hazards and risks. Other considerations are clearly needed to verify how pertinent some of those studies might be to this ultimate task.

The proposal should be completed by a pledge to consider only studies with transparent data and meeting the proven operational standards of genuine scientific evidence of causation. These include warrants of authentic measurements relevant to the stated objective - in this case human hazards and risks -, with verifiable negligible error rates, control of confounding externalities, reproducible results and more, as discussed extensively elsewhere.[7] Pace Hume and absolute causation, none of the effective technologies sustaining civilization would be possible if the supporting scientific evidence were not validated by the combined causal force of those warrants. Experiments and observations would be constrained by conjectures however expert, but unattractive to any entrepreneur searching to invest in new functional technologies. For equal and stronger reasons, untested conjectures must be unacceptable as the foundations of fair public health policies and regulations.

The standards of scientific evidence just mentioned are not abstruse philosophical propositions but sensible logical yardsticks common people implicitly or explicitly observe when buying at stores or pumping gas. They are also enshrined in the 1993 Daubert opinion of the US Supreme Court, which defines the minimum standards for evidence admissible in federal courts.[9] It would be most incongruous if EPA rules and

regulations were not compliant with the Daubert definition of admissible evidence, both to observe federal law and as institutional diligence to safeguard the Agency and the public treasury against potential court challenges.

The proposed rule further highlights EPA's intention to make transparent and public the choices and assumptions of mathematical models attempting to quantify human hazards and risks, or environmental problems and remediations. Such intention is most important, for those models can be exceptional tools in concealing obfuscation, if improperly used. Based on different mathematical and statistical constructs, the models utilize observational and causal experimental data from a variety of studies in various biological system including humans, or from environmental sources. Various models include: Benchmark dose, One hit, LMS, constrained LMS, maximum likelihood LMS, Weibull, constrained Weibull, Logistic, Probit, Poisson, Normal and many more models and variants. Each model represents a different x/y distribution, resulting in a different plot or graphic visualization of its mathematical function.

The classical instance in cancer risk assessment is to fit scant dose/response data from animal tests run at default assumptions and maximum tolerated doses (MTDs) into the mathematical functions of models, from which to infer extrapolations to the low level doses people may actually experience. MTD dose/response data can be made to fit virtually any of these functions, but so fitted functions result in low-dose extrapolations contrasting by several orders of magnitude.[10] Theoretically the choice of a model could be validated by reliable mechanistic evidence of the underlying biological processes, but the utter complexity of possible mechanisms make such evidence generally speculative. In practice, the choice appears to depend on whether low-dose extrapolations suit the ideological, conjectural or precautionary disposition of a risk assessor or of an Agency policy. The choice is clearly arbitrary and blindly judgmental at best, and an effective way to disguise arbitrariness with mathematical mesmerizing.

Dose-response models and bioassays in rodents provide the illusory comfort of inexistent science to arbitrary decisions, very similar to the imaginative use of weight-of-evidence, read across, meta-analysis, QSAR and similar judgmental devices that have consumed so many expert careers over the last decades. All reflect an obdurate refusal to admit that testable objective conclusions are not always possible, for science cannot provide relevant answers without relevant data. Without such data, models remain instruments of obfuscation and not of transparent disclosures. In its quest for responsible and legitimate conduct, EPA is well advised to consider models with

suspicion, and to reject models of any kind when the fitted data are not demonstrably relevant to human hazards and risks or to environmental scenarios.

In its quest for transparent accountability, the EPA also needs to address critically the common interpolation of safety factors during rulemaking, an issue not included in the proposed rule. Precautionary as they might be, safety factors are invariably arbitrary and major contributors to obfuscation, as they escape scrutiny behind precedent and claims of innocent precaution. An apt example comes from cancer bioassays in rodents, still used but now widely rejected as pertinent guides to human cancer hazard and risk assessment.[7] As mentioned, fitting their irrelevant results into model functions adds more fiction and bias to model outcomes, which are further corrupted by the precautionary introduction of several safety factors during rulemaking.[7] These are the most significant and arbitrary adjustments in rulemaking, geared to identify and permit the minimal exposures compatible with useful applications of a regulated entity. Being achieved by ad hoc manipulations of safety factors during rulemaking, the definition of such minimal exposures obviously is achievable without any input from bioassay and dose-response models, whose elimination from hazard and risk assessment ought to be seriously considered.

Seeking legitimate and ethical transparency, the EPA would be well advised to reject fictional inputs to its rulemaking and policies, including default assumptions. Its entire regulatory process could be simplified with separate guidelines for a) actions backed by independent and testable scientific evidence, mostly derived from acute and sub-acute tests in animals and humans; and 2) actions backed by judgmental precautionary considerations about unknown and unknowable chronic effects of putative hazards.[7] Anxieties about such hazards will continue to call for precautionary regulations. Those should rely not on pseudo-science, but on transparent tradeoffs between the least exposures compatible with utility and social perceptions of affordable precaution. Arguing to the contrary seems perverse in an era of regulatory accountability.

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