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Cranor's Reply

Merz and Frey's review of *Regulating Toxic Substances*,¹ while summarizing some of my main points correctly, suggests that they may have a different view of the legal/regulatory environment than was articulated there. This may lead to some differences between us. While some regulatory safety statutes require manufacturers to have government approval before their products are permitted into commerce, this may be less significant than seems presupposed in their review.² Many, perhaps most, substances have come into commerce or the environment as products, byproducts, contaminants or pollutants without extensive required testing for effects on human health or the environment.³ Legislation of the 1970's sought to address this, but it is not clear how successful it has been.⁴ Since the Toxic Substance Control Act was enacted in 1976, it is not clear how carefully substances permitted into the environment have been screened under its premarket approval procedure.⁵ Moreover, under most regulatory statutes, substances cannot be withdrawn from commerce, or exposures to pollutants or contaminants regulated, without the government's bearing a burden of proof to establish harm at current exposure levels.⁶ Also, tort law remedies are not available to plaintiffs who fail to carry both a burden of production to the satisfaction of a judge and a burden of

¹ Hereafter RTS.

² See Merz & Frey review *supra*, at 77–8 (hereafter M&F).

Sections of the Food, Drug and Cosmetic Act and the Federal Insecticide, Fungicide and Rodenticide Act require premarket approval of pesticides and the Toxic Substances Control Act requires premanufacture notifications for substances (including minimal testing) to be filed with the EPA, and then the EPA ordinarily has 90 days to identify substances that need further testing. Under these three laws, however, premarket review applies only to "new" chemicals. Office of Technology Assessment, *Identifying and Regulating Carcinogens*, 199 (1987) (hereafter OTA).

³ For pesticides, in 1987 there were about 600 that had been in the market prior to 1970 that had not been adequately tested at all. Even many registered since 1970 lack full toxicity testing; OTA, *supra* note 2, at 118–126.

⁴ *Id.*, at 3–20, esp. 18.

⁵ *Id.*, at 14 and 126–134.

⁶ *Id.*, at 199–200.

persuasion to the satisfaction of a jury, each of which presents barriers to tort deterrence of exposures to harmful substances.

In this legal setting, environmental scientists must provide evidence of harm before a substance can be regulated more stringently or before a tort suit is successful. Scientific standards of evidence tend to be much more demanding than legal burdens of proof.⁷ In recent years, widespread discussion has urged that scientific information should be required to document even more thoroughly that substances are harmful before regulatory or tort action is permitted. Given the current legal/tort environment and the much more stringent burdens of proof in science, such demands greatly increase the difficulty of regulating substances or of bringing successful tort suits. The coincidence of scientific and legal burdens of proof may have gone unnoticed, but together, these can have profound consequences for protecting human health. Merz and Frey may not fully appreciate this.

The science of risk assessment is both different from core areas of science and substantially permeated by uncertainties that carry unnoticed normative and other consequences.⁸ For example, if data and theories that would answer the question of whether X is a human carcinogen have a number of uncertainties, but one is not permitted to judge that it is a human carcinogen until all uncertainties have been removed, as typical scientific practice would have it, then the scientific position per force favors one side of the debate. Demands for more and better data, better mechanistic understanding and removing all or most uncertainties exacerbate this problem. Moreover, while stringent evidentiary demands are appropriate for the progress of science because they prevent mistakenly adding to the stock of scientific information, they are inconsistent with good environmental and public health policy — namely preventing false negatives and providing early warning of potential harms. (If the burdens of proof in the tort and regulatory law were reversed so that the safety of substances had to be established before human exposure was permitted, would parties currently arguing

⁷ RTS, at 55, 77 and 156.

⁸ *Id.*, at 13–38.

for more stringent science change their views?) Further, for statistically-based scientific information, the more scientists try to reduce false positives mathematically, the higher false negative rates are, other things being equal.⁹

There is an interaction between the *substantive* scientific standards of evidence and substantive legal standards of evidence. With the *Daubert* court, I argued that the *Frye* test for the admissibility of scientific evidence should be abandoned in the tort law.¹⁰ I argued, also similar to that Court, that only some scintilla of probative value should be sufficient to introduce evidence (even if it is insufficient to carry the burden of persuasion).¹¹ Should the threshold burden of production incorporate the demanding scientific standards of evidence and make this threshold similar to the "beyond a reasonable doubt" burden of proof in criminal laws?¹² I think not, but this will result if we deliberately or inadvertently incorporate scientific burdens of proof into legally required burdens. When low false positive rates are required, scientific skepticism and the mathematics of statistical studies work for defendants. Would Merz and Frey endorse this result? The tort law typically does (and should) strike a somewhat different balance between false positives and false negatives than the balance in research science, as well as a different balance than some courts and commentators are recommending. Further, when we assess risk for regulatory purposes, we should realize that the *rate* of assessment is important. If substances in commerce are harmful, and agencies are slow in assessing them, the harm continues. Thus, slowness is itself harmful. Yet, many recent recommendations would slow regulatory risk assessments beyond their present snail's pace.¹³

⁹ *Id.*, at 31–40.

¹⁰ *Id.*, at 60–71.

¹¹ *Id.*, at 77.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S.Ct. 2786, 2798 (1993): "[I]n the event that the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true the court remains free to direct a judgment...."

¹² RTS, at 76–78.

Finally, because of the uncertainties and the complexity of risk assessment, mistakes will result from our environmental science and regulatory activities. Mistakes will result because of evidentiary problems or because we have evaluated toxic substances too slowly — or, if we adopt expedited procedures, too quickly.¹⁴ I agree with Merz and Frey that it is difficult to find evidence of these kinds of mistakes and their rate.¹⁵ Epidemiological and other scientific studies can be negative even when substances are harmful.¹⁶ Thus, we are frequently surprised by the toxicity of products in our midst; this suggests that false negatives are a problem.¹⁷

The issue is not: Will mistakes be made, but which ones? How shall we err? How do we *design* assessment procedures and legal institutions to prevent *which* mistakes? As I assess some approaches, the coincidence of legal and scientific burdens of proof strongly tends to predispose legal decisions to more false negatives than seems desirable. Of course, there are now false positives as well. Yet, one political difference between false positives and negatives is that the former tend to have a built in constituency (firms whose products may cause harm), but false negatives do not (because isolated individuals who suffer harm are unlikely to discover their common cause). For both political and scientific reasons, false negatives are not easily identified. Thus, “I... suggested... modifications in complex existing or recommended procedures in institutions to try to achieve a more appropriate balance of these kinds of mistakes.”¹⁸

¹³ *Id.*, at 115–126.

¹⁴ Merz and Frey appear to suggest a sharp distinction between the presumed policy — or moral — neutrality of risk assessment and risk management. Yet if the arguments of RTS are correct, this separation is not easy; RTS, at 23–28.

¹⁵ Whether the costs of underregulation are greater than the costs of overregulation is difficult to answer; M&F, at 76. Partly this is a monetary question; partly it is a non-monetary social question — how we view costs of more expensive products (or their loss) versus how we view any social or human costs of increased exposures to toxic substances. Thus, it will be difficult to obtain adequate empirical data on this issue.

¹⁶ RTS, at 31–39 & 136.

¹⁷ E. W. Lawless, *Technology and Social Shock* (1977).

¹⁸ RTS, at 134. Merz and Frey's comment about preventing “paralysis . . . [so that

I argued that regulatory agencies should adopt faster risk assessment procedures and rely on consistent default positions and policy judgments to address uncertainties in the science.¹⁹ (Risk assessments relying on default procedures need not be inconsistent as Merz and Frey suggest — agencies currently follow such procedures, often as a matter of administrative procedure.) Also, appellate courts should recognize the need for agencies to rely on such approximations and expedited scientific methods.²⁰ Such modifications in practices and procedures could give somewhat greater weight to avoiding false negatives than at present without a major overhaul of either regulation or tort law.

Finally, it is important to recognize the complex relationship between the tort and the regulatory law. I agree with Merz and Frey that regulatory agencies in theory are better situated to judge complex risk tradeoffs and that tort law is not and should not be seen as a substitute for many reasons. However, agencies are subject to powerful political pressures that can undermine a fair consideration of issues. Given these and other problems, tort law, despite its “blurred signals to firms,” should backup regulatory law, and it should not be so hamstrung by implicit scientific burdens of proof, restrictive admissibility rules or unwise preemption rules as to preclude this vital function.²¹

we can] take action such as the marketing of a new drug or chemical before all risks are known or well-characterized” is puzzling; M&F, at 79. It suggests that I have urged more stringent premarket regulations (which I have not). Identifying and controlling potentially harmful substances already in commerce or the environment seem the more immediate issues.

¹⁹ RTS, at 137. Merz and Frey note that uncertainties can only be “reduced” by data and information. I tried to use the phrase “addressing uncertainties,” but occasionally used “reduced;” RTS, at 136. Nonetheless, there are different kinds of uncertainties. Some can be addressed in the short run by choices — choosing different models consistent with complex regulatory aims — while others are addressed by measuring more carefully, by better data, etc.

²⁰ RTS, at 147–151.

²¹ Merz and Frey call attention to recent cases which permit regulatory law and proceedings to preempt state tort actions. For reasons indicated here and in the book, this does not seem to be a desirable trend. *Id.*, at 63–66.

As noted by Merz and Frey, a moral view underlies these recommendations. Many in the regulatory arena implicitly adopt a utilitarian approach to evaluating institutions and public policy. But this paradigm tends to underprotect individual welfare because its main focus is overall social efficiency (cost-benefit analysis is a bastardized version of it). Thus, severe harms to a few can be outweighed (in principle) by minor benefits to many, and the distribution of benefits and burdens of a social policy are not necessarily a part of the theory.²² Utilitarian theories must be augmented or rejected because of these concerns. Theories of justice would give greater, but not necessarily decisive, weight to protecting individuals from the harms of toxic substances. However, I stopped short of suggesting a full rights-based alternative, and I stopped substantially short of claiming that “the imposition of risk on any member of society is immoral,”²³ a view to which I do not subscribe.

Thus, I argue for a change in paradigms regarding the amount of scientific information to be legally required both to regulate and to recover in tort — as well as for a change in how we think about such issues morally. Together, such paradigm changes will shift environmental health protections to fewer false negatives, albeit with the possibility of more false positives. Such institutional changes would improve current procedures and correct present trends.

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²² *Id.*, at 163–168.

²³ M&F, at 79.

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