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Neonatology and the specter of the law

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1. Introduction

When I began my career with dual training in bioethics and law, my research and clinical interests were focused on the suffering of terminally ill adults due to unwanted treatment and how perceptions of law among health care providers contributed to this problem. A central goal of my work was to try to prevent situations where physicians would aggressively continue to treat patients in ways contrary to their expressed wishes and ignore the attempts of family members to implement the preferences of their loved ones. It was apparent that some physicians were so anxious about the impact of legal factors on their practice that they were willing to tolerate additional suffering of patients to protect themselves. Further, I suspected that many of these physicians were not well versed in the nuances of applicable laws and were making these judgments with inaccurate information.

Hence my research was designed, in part, to dispel misperceptions by physicians of legal constraints on their practice and encourage them to educate themselves about law. I also hoped to suggest that some physicians modify their approach to cases of serious illness to evaluate all elements of the case proportionally, carefully considering the impact of suffering on both patients and families, rather than ascribing excessive importance to the impact of legal factors. Later in these pages, I will briefly describe some results of this research regarding cases of adult patients. As I became involved with ethical issues in neonatology, however, I rapidly recognized that both health care providers' perceptions of the legal rules, and the rules themselves, were markedly different regarding treatment decisions for neonates. I also observed that the reactions of families of neonates sometimes differed from reactions of families of critically ill adults. These recognitions have caused me to reflect on these differences and their implications for both research and health policy addressing the interactions between neonatal medicine and the law.

In this commentary, I will first review the history of the controversies about treatment decisions for infants with genetic and chromosomal aberrations which resulted in the federal and state laws now known collectively as the Baby Doe rules, as well as the ongoing dispute within the pediatrics and bioethics communities about clinical implementation of these rules. Second, I will examine briefly the current research on outcomes in extremely preterm infants with a focus on its implications for comparing international cultures on the practice of neonatology, as well as predictions of mortality and morbidity. Third, I will describe and discuss my own research about the effects of legal perceptions on medical decision making for terminally ill adult patients, and evaluate its implications for decisions about neonates. Fourth, I will attempt to draw some conclusions from the preceding sections and offer a few observations from clinical experience about how neonatologists may differ from physicians who treat older children and adults, as well as how the practice of neonatology coexists with serious legal constraints amid an environment of substantial medical uncertainty. Finally, I will look toward the future by suggesting a partial research agenda for addressing some of the concerns raised by these discussions.

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2. Controversy about the Baby Doe rules in the pediatrics community

The origins and evolution of the Baby Doe rules, and court decisions addressing relevant clinical cases, have been extensively chronicled elsewhere in the literature [1–7]. The cases triggering these rules arose in the early 1980s from two neonates with the following clinical presentations: tracheoesophageal fistula combined with trisomy 21, and meningomyelocele combined with microcephaly and hydrocephalus [1]. Essentially, the rules provide that non-treatment of neonates is justified only in three exceptional cases: first, if the ". . . infant is chronically and irreversibly comatose;" second, if provision of treatment ". . . would merely prolong dying, not be effective in ameliorating or correcting all the infant's life-threatening conditions, or otherwise be futile in terms of the survival of the infant;" and third, if provision of treatment ". . . would be virtually futile in terms of survival of the infant and the treatment itself under such circumstances would be inhumane" [1,8]. Further, the Baby Doe rules provide that "appropriate nutrition, hydration, and medication must always be given" [1]. Following legal challenges to their original 1984 version, the Baby Doe rules have been modified and are now technically optional, but compliance is essentially required for institutions receiving certain types of federal funding; the rules are subject to enforcement by state child protective services [8–12]. An emerging issue during the past decade is the change in types of patients for whom the Baby Doe rules apply, and are most often controversial. Previously, the legal focus of the Baby Doe rules was on infants with genetic and chromosomal abnormalities; today, issues of extreme preterm birth dominate the difficult cases in most NICUs. This transition has heightened debate among neonatologists regarding the propriety of practice guidelines endorsed by the American Academy of Pediatrics (AAP).

In 1996, the Committee on Bioethics of the AAP published its opinion about treatment decisions for critically ill infants in the wake of Baby Doe [13]. The Committee asserted that decision making for children of all ages should be individualized according to the best interests of the child as determined by parents or guardians; further, they argue that this position is fully consistent with the Baby Doe rules and that persons who disagree misunderstand these rules [13]. This position has been rejected by bioethics scholars, including Loretta Kopleman, who claim that a careful reading of the Baby Doe rules clearly removes a substantial amount of discretion from parents and physicians confronting treatment decisions for seriously impaired newborns; she further argues that this result was the intent of the Reagan administration when it proposed the original rules, and that regulatory matters affecting treatment for newborns are inevitably intertwined with the politics of abortion [1]. Kopleman notes that the sole quality-of-life criterion allowed by the AAP Committee is that treatment need not be provided when the infant is "chronically and irreversibly comatose." She argues that this criterion is inadequate to enable a humane and reasonable determination of the best interests of the child as commonly understood [1]. Citing the Committee's reliance on the concept of futility as a way to introduce a best interests standard, Kopelman meticulously picks apart this reasoning by comparing the actual language of the regulations to the AAP interpretations [1]. Specifically, it is most telling that the Committee seems to ignore the point that a clear reading of the Baby Doe rules demonstrates that futility may legally be invoked only when it refers to cases in which the infant will die *with or without* treatment [1]. Further, the rules also require that appropriate nutrition, hydration, and medication be provided, employing a restrictive interpretation of the word "appropriate" [1]. Kopleman and her colleagues have performed empirical research that supports her arguments. This survey of practicing neonatologists indicates that 76% of respondents believed that the Baby Doe rules were not necessary to protect the rights of handicapped infants and 60% believed that the rules interfered with parents' right to determine what treatment was in the best interests of their children [14]. In analyzing hypothetical cases, up to 32% of respondents reported their judgments that maximal life-prolonging treatment was not in the best interests of the infants described, but that the Baby Doe rules required such treatment nevertheless [14].

Joel E. Frader, an eminent bioethicist and pediatrician, both supports Kopleman's arguments and adds useful political context. Frader notes that the AAP leaders in 1984 ". . . felt that they had to support the 'compromise' language of [the rules] out of fear of even more intrusive and controlling legislation" [2]. He also regards the language of the Committee's opinion, suggesting that their views are consistent with the Baby Doe rules, as ". . . perhaps more wishful than anything else" [2]. Thus, in some sense the rules can be viewed as a best-attainable compromise amidst a highly-charged atmosphere of media coverage, strong public reactions, and a political agenda to exercise

greater federal control over certain types of medical decision making. Although explaining this political compromise well, Frader makes clear his own view that "... federal intrusion on factually and morally disputed decisions in the NICU was and remains a bad idea and should go away" [2]. Others are less concerned than Frader, claiming first, that the Baby Doe rules are enforced by states' child protective services and that such formal actions have never been taken, and second, that the recent judicial opinions strictly interpreting the rules apply to only a few jurisdictions and that best interests remains the preferred standard elsewhere [5, 15,16]. These two arguments will be addressed separately. Even though it appears that the primary method of enforcement for the rules is CPS agencies, there is no language in the rules that limits their enforcement by CPS [6]. More important, even though scholars report no knowledge of formal prosecutions by CPS for violations of Baby Doe rules, there is ample anecdotal evidence (including my own personal experiences as an ethics consultant) indicating that CPS agencies scrutinize carefully the medical records of neonatal cases during periodic audits and aggressively pursue investigations when the records contain any ambiguity [5, 6]. Further, complaints filed by families or other interested parties about cases where it is believed treatment was terminated for improper reasons can be pursued to extreme lengths by CPS before the legitimacy of such reports can be determined (depending on the personal tendencies of investigators). Such investigations by CPS, even if not resulting in prosecution, clearly have a chilling effect on the practice of neonatology by many physicians. As Kopleman has noted, federal regulations supported by appellate courts and CPS investigations "... can be powerful forces in shaping behavior" of health care providers [17]. The impact of such a chilling effect should not be underestimated.

In order to address the argument that existing legal precedents are few in number, apply in only a small number of jurisdictions, and therefore have limited impact, it is necessary to describe briefly the two recent appellate opinions interpreting application of the Baby Doe rules. The first case, *Montalvo v. Borkovec*, is a 2002 decision from the Court of Appeals of Wisconsin, District One, in which a neonate born at 23 and 3/7 weeks gestation was resuscitated at birth, apparently against the wishes of his parents [15]. Essentially, the parents' claim was that the decision to resuscitate should have been theirs as parents rather than being left to the sole discretion of the physicians. Because Wisconsin had accepted federal funding under the US Child Abuse Protection and Treatment Act (CAPTA), the court applied the Baby Doe rules (a subsection of CAPTA) and held that "the implied choice of withholding treatment [resuscitation at birth], proposed by the plaintiffs [parents], is exactly what CAPTA prohibits" [15,18]. Both the Supreme Court of Wisconsin and the US Supreme Court later declined to review the *Montalvo* decision, limiting its value as precedent to the district in which the court sits.

In the second case, *Miller v. HCA*, a 28-year-old woman went into labor approximately 23 weeks into her first pregnancy [16]. Although it is clear that the parents, physicians, and hospital administrators had several conversations during labor about risks to the infant's health and her prognosis, some of the precise facts remain in dispute. Both parents informed the physicians during labor that they were refusing resuscitation of the infant. The father later testified that a hospital administrator told him the hospital had a policy that required resuscitation of any baby weighing more than 500 grams and that he would have to remove his wife from the hospital in order to prevent resuscitation of the infant [4]. The medical team agreed among themselves that they would wait to make a resuscitation decision until the baby was born and could be examined. When the baby was born she weighed 615g, cried spontaneously, had "no unusual dysmorphic features," with Apgar scores of 3 and 6 at one and ten minutes, respectively [4]. The parents did not refuse any indicated treatments after birth. Subsequently, the infant developed a Grade III/IV intraventricular hemorrhage and hydrocephalus; her current condition presents severe mental and physical impairments, including cerebral palsy, seizures, severe mental retardation, blindness, recurrent shunt placements, and incontinence, with no expectation of improvement [3,4]. The parents sued the hospital and its parent company for battery and negligence. The jury concluded that the resuscitation had been performed without consent and awarded the family $29.4 million for medical expenses and $13.5 million in punitive damages [4]. The judgment was overturned on appeal and the family appealed to the Texas Supreme Court. The Supreme Court described the issue as requiring it "... to determine the respective roles that parents and healthcare providers play in deciding whether to treat an infant who is born alive but in distress and is so premature that, despite advancements in neonatal intensive care, [he or she] has a largely uncertain prognosis" [16]. The court determined that "... a physician who is confronted with emergent circumstances and provides life-sustaining treatment to a mi-

nor child, is not liable for first obtaining consent from the parents" [16]. In other words, informed consent for resuscitation is not required in such emergent circumstances because the parents do not have the option of refusing. The decision is a narrow one and provides little guidance except that neonatologists are permitted to make a decision about resuscitation immediately after birth in cases of extreme prematurity. As George Annas has observed, "... nothing in the decision requires the presence of a neonatologist at the delivery. More troubling, the court implies that life is always preferable to death for a newborn and could be interpreted in the future to support the neonatologist who always resuscitates newborns, no matter how premature or how unlikely their survival is without severe disabilities" [16].

It is notable that both appellate court decisions have interpreted the applicability of the Baby Doe rules to cases of extreme preterm birth rather than the moderate genetic anomalies that first spurred the passage of the rules. Because there is little significant opposition today (among the public or medical community) to providing full treatment for infants with moderate health problems like those in the cases that originally generated the rules, while cases of extreme prematurity present risks of catastrophic and permanent disability, it may be time to consider whether the same criteria should be applied or whether humane public policy requires a revised set of criteria. Kopelman concludes her arguments with a statement of principles that clearly describes the goal: "The Baby Doe rules should be challenged by the AAP because they impede individualized and compassionate care for children advocated by the AAP, and they give too little consideration to parental consent, clinical judgment, and duties to minimize unnecessary suffering and treat others the way we wish to be treated" [17].

3. Cultures of neonatology and the prediction of clinical outcomes

A central factor in the social policy struggle about laws regulating the practice of neonatology is the uncertainty among physicians when attempting to predict morbidity and mortality among infants born with extreme prematurity. This controversy is further complicated by high variability in the outcomes reported in the medical literature from developed countries, especially at the threshold of viability – births at < 23 weeks gestational age. For Europe, data from the EPICure Study Group in the United Kingdom and Ireland (published in 2000 and 2005), is currently thought to be the most valid and reliable in this population [19–21]. Among 22 week gestation infants born alive, the EPICure data indicate a prevalence of survival-to-discharge of one percent and survival without overall disability at 30 months at five percent of NICU admissions (0.7 percent of live births) [20]. Follow-up data from EPICure at age six years indicates a prevalence of survival without overall disability at 12 percent within this tiny population (0.0008 percent of live births) [21].

In stark contrast to the EPICure results, are data on 22 week premature births from Japan (collected only from government-recognized perinatal centers) suggesting an overall 28 day survival rate of approximately 32 percent [22]. Other research, from the Vermont-Oxford Network, has reported survival to discharge only in terms of birth weight rather than gestational age; this group found infants born at < 500 grams (50th percentile at 22 weeks) too immature to survive with current technology [23]. Another group, Seri and Evans, has combined these criteria to constitute what they call a "gray zone" of decision making, and proposed a dual measure of < 23 weeks gestation *and* $<$ 500 grams [24]. These varying methodologies have highlighted the depth of lingering uncertainty about the best measures for evaluating this population. Further complicating matters are anecdotal reports from professional conferences suggesting that in some parts of Europe, infants born at < 23 weeks are routinely treated with good results (personal communication from Stephen M. Baumgart, MD).

However difficult it is to predict survival, predicting severe morbidity appears less so. John D. Lantos has noted that there is a group of about 10 percent of neonates about whom predicting survival is "little better than chance" [25]. Yet, when it comes to predicting severe disability the predictions are considerably more reliable. Rates of survival (among all live births) with no disability at six years in the EPICure study population were 0.0008 percent at 22 weeks gestation, one percent at 23 weeks, and three percent at 24 weeks – data that Vohr and Allen have described as "troubling" [26]. Lantos and colleagues have concluded that "... clinical predictors of medical futility are not very accurate if futility refers only to survival. However, if it refers to neurologically intact survival, the doctors and nurses were very good at foreseeing the future" [25,27]. This phenomenon makes determinations of "futility" as defined by the Baby Doe Rules, potentially even more controversial.

These international data may suggest that trends in some developed countries are moving toward aggressive treatment for extremely preterm infants regardless of gestational age and that higher survival rates (if not an artifact of flawed methods) indicate a divergence of neonatology practice according to national, regional, or even local cultures. Individual countries and cultures may be going their own ways when determining treatment thresholds. Contrary to the general trend toward uniformity in medical standards of care, in neonatology the opposite of standardization may be occurring. This counter-standardization according to geographic and cultural variables has been noted by John Lantos as one of the emerging challenges of both research and practice in neonatology (a concept I first heard from Dr. Lantos during a plenary session at the 20th Annual Bioethics Summer Retreat in Santa Rosa, California, June, 2008). It appears likely that this also accounts for the position of the International Liaison Committee on Resuscitation that its guidelines on neonatal resuscitation "... must be interpreted according to current regional outcomes and societal principles" [28]. I will now turn to a summary of research findings on physicians' legal defensiveness and knowledge of law.

4. Research on physicians' legal defensiveness and knowledge of medical law

Our research group has defined legal defensiveness as the aggregate of factors encompassing physicians' perceptions and practices regarding abatement of life-sustaining treatment, including medical, ethical, legal, social, psychological, and spiritual factors [29].

Some research issues that prompted these studies include: the prevalence of legal defensiveness among physicians treating critically ill adults; the adequacy of physicians' knowledge of relevant laws; whether accuracy of physicians' legal knowledge is associated with sources of legal knowledge; whether physicians think that law forces them to alter their practice patterns; whether improved knowledge of law may diminish legal defensiveness; and whether legal defensiveness, in the broadest sense, affects physicians' assessments of medical futility in ways that have an impact of patients' and families' ability to exercise self-determination in end-of-life decisions. Briefly, our methods included a 67-item questionnaire assessing physicians' responses in the categories of medical law, medical futility, and physician anxiety regarding dying patients. The instrument included a 10-item quiz designed to measure objectively some important substantive laws relating to end-of-life medical treatment. In response, we received 301 usable questionnaires from faculty and house staff who were actively practicing internal medicine, oncology, and surgery in tertiary care medical centers around the state of Texas. Six items from the instrument were found to be significantly intercorrelated in measuring general legal defensiveness and they were combined into a composite score– the "LD6 scale." Results on this scale form the basis of our measure of legal defensiveness. Additional details about methodology can be found in our work published previously [29–31].

Our findings in this population indicate that approximately 25 percent of responding physicians reported an extreme level of legal defensiveness as measured by the LD6 scale (see Fig. 1) [29]. Further, extreme legal defensiveness was substantially lower among physicians 1) who treated a large number of terminally ill patients, 2) who had more years of clinical experience, 3) who reported that they felt "adequately trained to deal with dying patients," and 4) oncologists, as compared with other internists and surgeons. Regarding knowledge of medical law the mean score on the quiz was 53.9 percent, indicating that the average physician answered about half the questions correctly. The source of physicians' legal knowledge was also found to be important – those respondents who reported receiving *none* of their information about law from other physicians were twice as likely to get a high score on the law quiz as were those who reported receiving *at least some* of their information about law from their physician colleagues. A very interesting finding was that those physicians who demonstrated better knowledge of relevant law (by scoring 70 percent or better on the quiz) were significantly less likely to report extreme legal defensiveness. These findings enabled us to construct a logistic regression model estimating the effects of these (and other) factors on the probability of extreme legal defensiveness. Using this model, the most defensive group would be early-career, non-oncologist physicians who had treated relatively few terminally ill patients, who said they did not feel adequately trained to deal with dying patients, and who scored below 70 percent on the law quiz.

We repeated the major elements of this study in Denmark several years later and compared the results to those from the United States [32]. Our findings indicate that the Danish physicians sampled demonstrated significantly better knowledge of Danish laws relevant to their practice, and that they reported significantly lower levels of legal defensiveness. These findings are

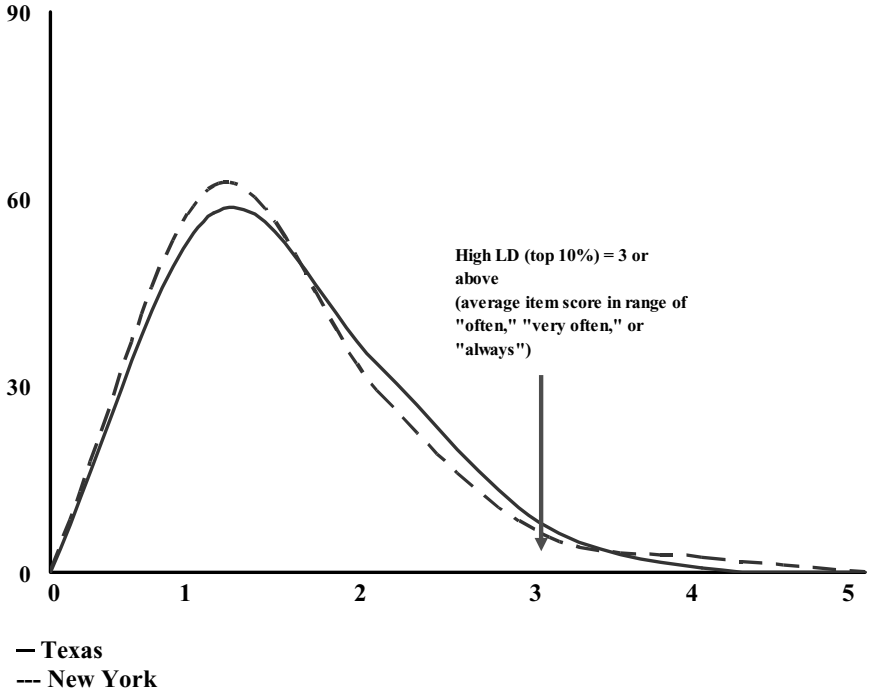

Fig. 1. Distribution of legal defensiveness scores in Texas and New York physician surveys.

thus consistent with results from the US study showing that legal defensiveness and knowledge of medical law are inversely related.

In addition to measuring the influence of law, we also studied the effects of physicians' conceptions of medical futility. We asked physicians to assign a percentage of likelihood of success below which they would consider a treatment futile. Responses varied from zero to 60 percent, with most responses being in the one to 10 percent range [31]. One set of responses emerged as especially significant – 20 percent of responding physicians reported that their threshold of futility was zero percent. That is to say, these physicians would not view a treatment as futile if a one-in-one-million chance of success exists – in essence, a denial of futility. As we stated earlier, "in scientific terms, this is an extraordinary statement. It begs the question how could anyone know in advance when the probability of treatment success is actually zero? Perhaps more to the point, how would a doctor, who held to that standard of futility, act?" [31]. We analyzed the data and found that six physician responses and characteristics were significantly associated with this denial of futility: 1) male; a religious participant; feel not constrained by medical law; equate physician failure with inaction; are uncertain about efficacy vs. benefit; and, always remain emotionally detached from dying patients. It was especially interesting to us that this group of physicians reported *not* being constrained by law at all, but apparently were affected by other perceptions and attributes. These findings raise intriguing questions about how such physicians actually practice medicine, especially how they interact with patients and families in discussions about end-of-life decisions and the degree to which patient self-determination is respected.

We next asked ourselves how extreme legal defensiveness might affect physicians' perceptions of futility and how that might, in turn, affect interactions with patients and their families. Analyzing the same data, we found that a majority of physicians indicated that the probability of success defining futile treatment should generally be *lower* for patients with potential to benefit *more* from life-sustaining interventions (e.g., patients who are sentient), and *higher* for patients with less potential to benefit (e.g., patients in a permanent vegetative state) [30]. Stated another way, most physicians perceive longer odds worth pursuing for greater potential gain – a position that seems logically consistent with most patients' rational self interest. However, physicians with attitudes of extreme legal defensiveness did not fit this pattern. Instead, they tended to define futility in a manner that would maximize physicians' discretion to oppose patient preferences for abatement of end-of-life treatment. These findings sug-

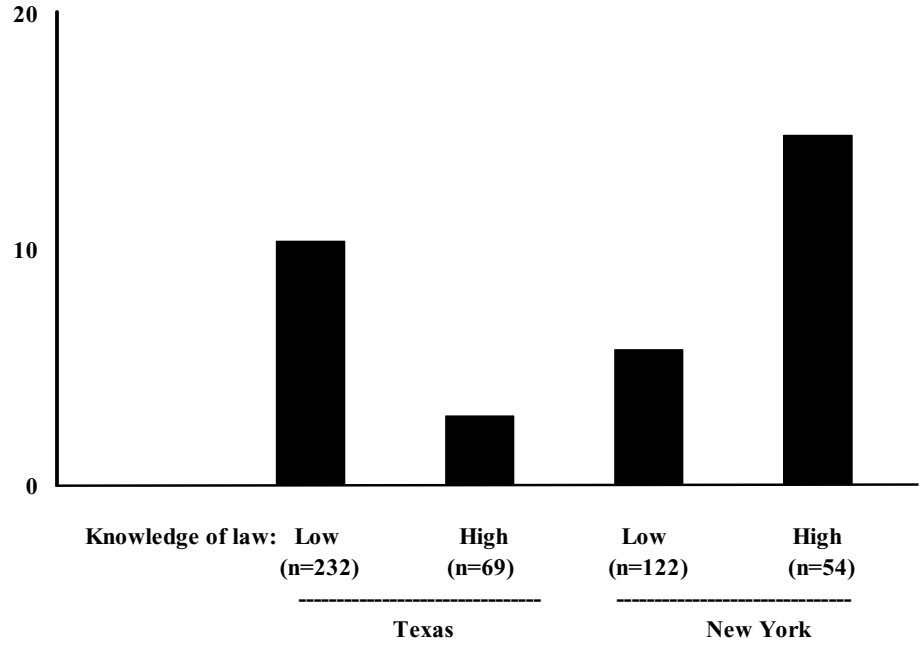

Fig. 2. Physicians' legal defensiveness by knowledge of medical law regarding end-of-life treatment in two states. Percent with high legal defensiveness.

gest that physicians who are extremely concerned about legal implications take an adversarial position in their consideration of medical futility issues – an attitude that anticipates conflict with critically ill patients and their surrogates. Although not definitive, this analysis suggests that some physicians may inappropriately use their prerogative over medical futility as a means to guard their professional autonomy against perceived threats, and may thus limit patients' self-determination under the cloak of legal fears.

Another phase of our research replicated major portions of the previous study in a different state. Because the first study had been carried out with physicians in Texas, we wanted to ascertain which of our findings would pertain if the same questions were asked in a state with markedly different legal constraints – New York. The New York study surveyed physicians from two tertiary care medical centers in different geographic regions of the state and yielded 180 responses [33]. In general, the New York physicians performed comparably to their Texas counterparts on the quiz of medical law. Similarly, on the legal defensiveness scale the overall distribution of scores was quite comparable (see Fig. 1 for a comparison of data from Texas and New York). Like in Texas, general reported legal defensiveness was lower among New York physicians with more than 20 years experience in practice. However, when we assessed the interaction between legal defensiveness and knowledge of law, the results were strikingly different.

In aggregate, the New York data show an inverse relationship to those from the Texas study. That is, in Texas performing well on the law quiz was associated with *lower* legal defensiveness, while in New York, higher scores on the law quiz were associated with *higher* legal defensiveness (see Fig. 2) [33] In order to understand this difference, it is necessary to describe two important differences in the laws of New York and Texas. First, unlike Texas and most other states, New York has never adopted a "best interests" standard for decisions making in cases of incapacitated patients who lack surrogate decision makers; nor has New York passed statutory laws recognizing a decision-making hierarchy (among family members and friends) for incapacitated patients who have not signed advance directives expressing whom they prefer to make decisions on their behalf. Second, in the 1988 *O'Connor* case, the highest court in New York established a standard of "clear and convincing" evidence with a restriction that evidence for decisions about life-sustaining treatment must be determined solely by subjective criteria – that is, only explicit, precise, and firm statements from the patient herself are legally acceptable for abatement of treatment, especially in cases of artificial nutrition and hydration (see Appendix 1 for a discussion of the *O'Connor* decision) [33,34]. One question on the New

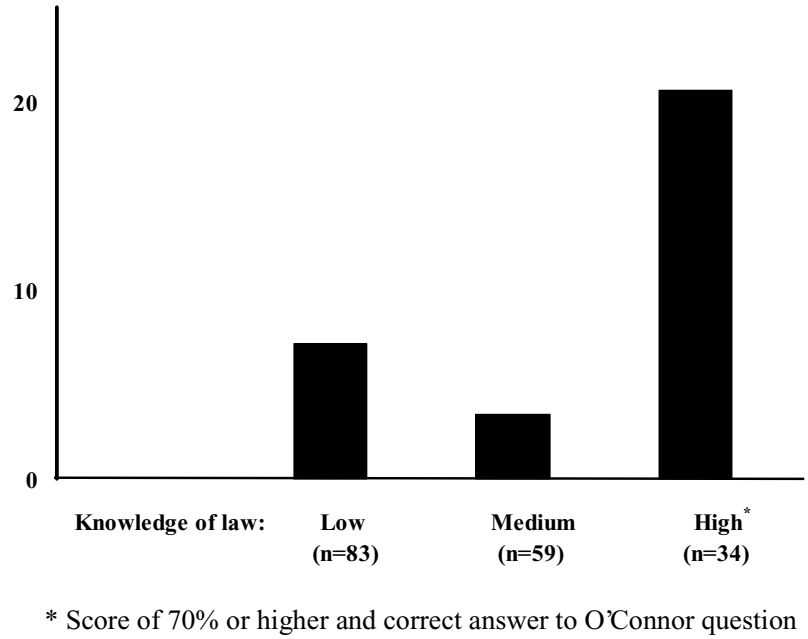

Fig. 3. New York physicians' legal defensiveness by knowledge of medical law regarding end-of-life treatment in two states. Percent with high legal defensiveness.

York version of our law quiz was designed specifically to test physicians' knowledge about the *O'Connor* case. To further examine the impact of New York physicians" knowledge of the *O'Connor* decision on their degree of legal defensiveness, we isolated a group of respondents, *post hoc*, who both performed well on the law quiz, and correctly answered the *O'Connor* question. As shown in Fig. 3, this subgroup of respondents were found to have the highest degree of legal defensiveness and, in fact, to account entirely for the contrasting pattern of association between legal knowledge and defensiveness in New York compared to Texas. When this subgroup of respondents was removed from the analysis, the association between knowledge and defensiveness in the remainder of the New York sample is consistent with that in the Texas sample (see Table 1); that is, as knowledge of law increases, legal defensiveness decreases. Thus, the significant overall interaction effect between state and legal knowledge is completely attributable to a subgroup of respondents who possessed accurate knowledge of law, including the specific implications of the *O'Connor* case [33]. Our findings suggest that New York's current laws exacerbate extreme legal defensiveness among knowledgeable physicians and that this may present a substantial barrier to family decision making and compassionate care for critically ill patients who lack capacity and have not prepared an advance directive. The similarities between this set of circumstances and the challenges of practicing neonatology under the Baby Doe rules is a stark one that I will discuss in the next section of this commentary.

I will now address some conclusions suggested by this research. First, the good news is that, in general, a majority of physicians (75 percent) are not extremely defensive about legal risks in their practice. Second, as physicians acquire additional clinical experience they appear to become less defensive about the law. Third, among the minority of physicians (25 percent) reporting attitudes of extreme legal defensiveness, taking time to study the relevant law may decrease defensiveness. Fourth, it is important for physicians to rely only on sources of legal information that are reliable. Fifth, physicians in the US may be more defensive about medical-legal issues than their European counterparts. Sixth, and more troubling, identifiable physician characteristics may be associated with taking positions about futility and/or legal risk that could minimize patient and family self-determination. Seventh, anticipation of possible conflict with patients and family may cause physicians' analysis of decisions be skewed toward maximum flexibility on the part of physicians to the exclusion of patient and family interests. Eighth, recognized differences in state laws can change *actual* legal risk and also have significant effects on *perceived* legal risk. Ninth, physicians' perceptions of legal risk and its impact on medical decision making is

a highly complex phenomenon that does not always conform to expectations of rational behavior. Finally, extreme clinical reactions to perceptions of law on the part of physicians – either being extremely concerned about legal risk or not concerned at all – may present substantial obstacles to patient self determination.

5. Comparing legal risk in the practice of neonatology versus adult medicine

My experience suggests that even among neonatologists there is a substantial range of legal defensiveness, but that the baseline for defensiveness is higher in neonatologists than among critical care physicians in general. That is to say, primarily because of the Baby Doe rules, neonatal practitioners as a whole have greater sensitivity to the legal risks of terminating life-sustaining treatment and tend to modify their practice accordingly, sometimes in conflict with their best medical judgment and parental assessments of patients' best interests. This indicates that the Baby Doe rules have had a substantial chilling effect on treatment decisions in cases where physicians think that further treatment for particular patients will have disproportionately small benefits and extreme burdens for patients and families. Recall that Kopelman's early study of neonatologists' attitudes shortly after the effective date of the Baby Doe rules supports this position [14]. In adult critical care settings there is also a range of legal defensiveness but, in contrast, research suggests that legal defensiveness will generally decrease as knowledge of pertinent law increases. The major exception to this trend is that in states like New York, where there are highly restrictive and specific laws, such high-visibility laws will also have a substantial chilling effect on clinical practice, especially decisions to abate life-sustaining treatment. Our research on anticipated conflict may also prove helpful in illuminating these issues – if legal constraints, perceived or real, create in the minds of physicians a posture of anticipated conflict with patients and families, such attitudes may undermine the important clinical goals of minimizing suffering of patients, promoting group process, and facilitating self-determination in decision making.

Environments in which critical care is practiced may also be affected comprehensively by legal defensiveness. Disputes among individual physicians and nurses about specific cases may spread and contribute to intra-unit tension and conflict. This may be partially attributable to differences in practice style generally, but in my experience can certainly be exacerbated by varying perceptions of legal risk among critical care providers. Moreover, individual nurses' and physicians' attitudes about these issues can affect the culture of an entire unit if practitioners are concerned that staff who disagree with their practice patterns may report activities they believe inappropriate to state regulatory or law enforcement officials. Decisions to abate life-sustaining treatment may be delayed or halted by such conflict between physicians and staff. In this sense, physicians and nurses with the highest legal defensiveness in a particular unit may limit abatement of life-sustaining treatment by default, with little regard for the interests of patients and families (and, in NICUs, the Baby Doe rules provide cover for such practice). In my view, this problem is especially acute in contexts with recognized elevated levels of legal risk, whether they be neonatal or adult settings. My clinical experience also suggests that substantial deficits in legal knowledge among practitioners in both neonatal and adult critical care settings persist. In environments of highest anxiety about legal risk, it seems unlikely that learning more about the actual constraints of the law will ameliorate defensiveness. Such study of law may in fact increase defensiveness in certain contexts, as our New York research suggests. In general, it seems to me that the degree to which the actual law is *targeted toward* specific clinical activities or particular specialties and sub-specialties (for example, terminating treatment for neonates or removing nutrition for adult patients in New York) the more anxious physicians will be about engaging in those types of activities. This explanation is consistent with both the findings of our research group and with those of Kopelman and colleagues.

To summarize, while it may be mostly unfounded and counterproductive for physicians to have excessive anxiety about the law in many other adult critical care contexts, fear of significant legal constraints in neonatal contexts may be quite reasonable because of the Baby Doe rules. As the oft-used saying goes, "it's not paranoia if they *are* out to get you." The trick for practitioners, of course, is determining the reasonableness of one's fears and acting appropriately. Unfortunately, while this internal debate about the law persists among providers, practicing optimal, ethical medicine may be impeded at the expense of patients' and families' well-being. Thus, unnecessary suffering may be the primary legacy of these highly restrictive rules. In neonatal contexts, the high level of clinical uncertainty about mortality and morbidity may also exacerbate the impact of legal defensiveness by causing clinicians

Table 1
Multivariable regression analysis[1] of effects on legal defensiveness

	Model 1: Main effects				Model 2: Interaction effect			
	Degrees of freedom	Parameter estimate	Standard error	t	Degrees of freedom	Parameter estimate	Standard error	t
New York compared to Texas	1	−0.12	0.07	$-1.78^{\dagger}$	1	−0.60	0.23	-2.59^{**}
Lawscore (number correct)	1	0.00	0.00	0.20	1	−0.01	0.01	-1.98^{*}
New York x lawscore interaction					1	0.01	0.00	2.17^{*}
	Model F = 4.87^{***} Adjusted $R^2 = 0.04$				Model F = 4.87^{***} Adjusted $R^2 = 0.05$			

Statistical significance: $\dagger p < 0.10$; $^{*}p < 0.05$; $^{**}p < 0.01$.
[1]Models are controlled for years experience and medical specialty.

to second-guess their decisions. This may explain to some degree the apparent divergence of neonatal practice in the United States when compared with other developed countries that have more uniform policies on the provision of critical care.

6. Toward the future: A research agenda

I will now present an overview of a possible research and policy agenda. An important threshold question is: To what degree there *really* exists an identifiable national consensus about social preferences for neonatal treatment under conditions of highly uncertainty mortality in extremely preterm infants? John Robertson has characterized the Baby Doe rules as the product of a societal "consensus of sorts" [3]. He argues that the Baby Does rules are an appropriate compromise between the general (and quite legitimate) commitment to "respecting human life regardless of disability," and the fact that the rules do not directly impose legal penalties on physicians but merely require states to set up protective procedures [3]. Yet, as Frader has noted, background behind development of the current AAP policy on Baby Doe suggests that the rules were the product of a forced political compromise to avoid substantially more punitive laws [2]. This tension evokes a phenomenon to which I have devoted a considerable amount of study – the tendency of health care providers and administrators to regard *perceived* legal constraints as *real* constraints [35]. Stephen Toulmin has described this propensity in health care institutions as follows: "the most efficacious social facts in the actual hospital situation are, in real life, *those perceptions themselves*, not the objective risks and needs as these might be assessed by some impartial, outside observer" [36]. Even Robertson has recognized this point by noting that many physicians, hospital administrators, and lawyers still perceive the rules as creating an absolute legal presumption in favor of treating children likely to have disabilities, and that "technically this was inaccurate, but it was not an unreasonable conclusion" [3]. The implications of this are more striking now, however, because there is much more social controversy and litigation regarding extreme prematurity than there ever was about application of the rules to genetic anomalies. This strongly suggests that it is time to revisit the Baby Doe rules at the public policy level.

My view is that the first choice would be to repeal the Baby Doe rules entirely and rely on the traditional approach that parents, with guidance from physicians, are the best arbiters of their children's best interests. But if that proves not politically feasible, Robertson has suggested another option – to change the burden of proof that must be met in order to treat a child over the parents' wishes [3]. From a practical perspective, in NICUs where the culture is dominated (*de facto*) by fear of the Baby Doe rules, parents currently have little or no input in most treatment decisions if they think such treatment would not promote the child's interest or would impose a disproportionate burden of suffering. Under such an approach, parents would have a presumptive legal right to have their decisions about the child's case respected unless the medical team could demonstrate by clear evidence that the child is likely to have a specified minimum level of cognitive functioning. Robertson's preferred standard for this minimum level is capacity of the child for "meaningful symbolic interaction or communication" [3]. Although a practical definition of this concept might be challenging to construct, the standard recognizes that we typically value humans largely because of our capacity for meaningful interaction with others [3]. Shifting the burden of proof in this manner would also mean that physicians and hospitals would not be liable if parents had second thoughts after making a good faith determination that treatment would not promote the child's best interests and the hospital respected their decision. If shifting the legal burden of proof is too impractical and repeal politically impossible, amending the Baby Doe rules to ac-

commodate a proportionality analysis would be a good alternative. Unlike the current restrictive Baby Doe rules, adding a specific provision whereby physicians and families were legally allowed to consider the relative burdens and benefits of continuing treatments for neonates would enable both a legal and ethical recognition of the burdens of suffering borne by survivors. A related set of issues would examine the reverse situation – where physicians think that further treatment would not benefit the child, would impose unnecessary suffering, and that the child will have minimal future capacity for interaction, while the parents insist on continuing treatment deemed to be non-beneficial. One further extreme complication is the "window of opportunity" problem, where some neonates pass through a period of medically correctable hemodynamic instability, and then stabilize with devastating effects, often lacking the capacity for meaningful interaction. Under a burden-shifting approach, a post-delivery evaluation period for the child would generally be indicated, and physicians could thus delay any abatement of treatment; meanwhile, however, how do physicians determine prospectively when the window of opportunity has passed and what are the legal implications?

The complex issues of medical perceptions of legal risk, and the responding proposals to shift the legal burden of proof or introduce regulatory proportionality, raise numerous research questions, including: 1) Can a sufficiently clear set of medical criteria be designed to enable a shift in legal burden of proof to succeed? 2) What is the current effect in clinical settings of clinicians' perceptions of the Baby Doe rules? That is, how do perceptions of legal constraints interact in the nursery with the clinical uncertainties of extreme prematurity? 3) Is narrowing the current "gray zone" of highest clinical uncertainty a scientifically realistic goal? 4) How do we best facilitate individualized decision making in parents? 5) Should the clinical practice of neonatology be more closely standardized and adjusted for legal risk? Can it be, practically? 6) What are the relative prevalence of physicians versus parents demanding that long-shot treatments continue, and how should this shape the law? How does parental (or physician) denial interact with these decisions in particular cases? 7) What are the effects of the *Miller* and *Montalvo* court cases on neonatologists' perceptions of legal risk and resulting changes in practice patterns, both within the relevant legal jurisdictions *and* nationally? 8) What are the implications and effects of ill-informed, aggressive press scrutiny on high-profile neonatal cases and how does this interact with legal concerns? [25]. 9) What is the appropriate balance between promoting neonatal life and ameliorating suffering? Is law the best means to accomplish this goal? Who decides? 10) If society chooses via legal rules to require physicians to treat (and parents to accept treatment for) even the most marginal cases, is there a duty to provide public funding to care for devastated survivors of extremely preterm birth? 11) What can we learn from the approaches to extreme prematurity in other developed countries and how can reliable comparative outcomes research be fostered? These and many other related questions should make clear the extreme complexity, multi-factorial nature, and interconnectedness of these issues. It is to be hoped that they will stimulate the search for solutions to these ongoing challenges, both in neonatal medicine and the law.

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Appendix 1

In *O'Connor*, the 77-year-old patient suffered multi-infarct dementia following a series of strokes and was unable to swallow food or water.[1] She had substantial cognitive impairment and clearly lacked decisional capacity, though her consciousness waxed and waned, ranging from being completely unresponsive to being reasonably alert and sometimes able to follow simple commands. Her condition was considered irreversible with no hope of substantial neurologic recovery. When physicians sought permission to insert a nasogastric (NG) feeding tube, Mrs. O'Connor's daughters, acting as her surrogates but not formally appointed as health care agent, refused to consent. The hospital sought a court order to insert the NG tube. At trial her two daughters testified that, while competent, their mother had repeatedly stated her wish to refuse medical treatment, saying for example that it was "monstrous" to

[1] *In re Westchester County Medical Center ex rel. O'Connor*, 72 N.Y.2d 517, 534 N.Y.S.2d 886, 531 N.E.2d 607 (1988).

keep someone alive by using "machinery and things like that" when they are "not going to get better." Reversing the two opinions below, in which courts had refused the hospital's request, the New York Court of Appeals found that the evidence of the patient's wishes was not clear and convincing and ordered insertion of the NG tube. Reaffirming the standard it had adopted in an earlier case, the *O'Connor* court embraced a particularly narrow subjective intent interpretation of the clear and convincing evidence standard, stating that "nothing less than unequivocal proof will suffice when the decision to terminate life support is at issue." Offering further definition of the standard, the opinion also states that there must be proof "that the patient held a firm and settled commitment to the termination of life supports under the circumstances like those presented." Under such a standard, if the patient is unable to predict with a high degree of accuracy her future medical circumstances, then the law dictates that her general wishes be ignored. A recently published *Legal Manual for Physicians*, jointly authored by the state's Bar Association and Medical Society, recognizes that *O'Connor* is the governing law for incompetent patients without health care proxies (unless the decision concerns a DNR order, in which case New York's DNR statute controls). The Manual goes on to state the prevailing view of the meaning of this rule at the bedside of dying patients: "When there is no clear and convincing evidence of the patient's wishes and no health care agent, nobody may authorize the withdrawal or withholding of life-sustaining treatment – not the family, not the physician or hospital, not even the court or a court-appointed guardian (except for guardians of mentally retarded persons . . .)."[2]

References

[1] L.M. Kopelman, Are the 21-year-old Baby Doe Rules misunderstood or mistaken? *Pediatrics* **115** (2005), 797–802.

[2] J.E. Frader, Baby Doe Rules (letter), *Pediatrics* **116** (2005), 1601–1602.

[3] J.A. Robertson, Extreme prematurity and parental rights after Baby Doe, *Hastings Center Report* **34** (2004), 32–39.

[4] G.J. Annas, Extremely preterm birth and parental authority to refuse treatment: The case of Sidney Miller, *New Engl J Med* **351** (2004), 2118–2123.

[5] I. Hurst, Baby Doe Rules (letter), *Pediatrics* **116** (2005), 1600–1601.

[6] F. Clark, Baby Doe Rules (letter), *Pediatrics* **116** (2005), 1601.

[7] F. Clark, Baby Doe Rules have been interpreted and applied by an appellate court (letter), *Pediatrics* **116** (2005), 513–514.

[8] Nondiscrimination on the basis of handicap; procedures and guidelines relating to health care for handicapped infants. HHS. Final Rules, *Fed Regist* **49** (1984), 1622–1654.

[9] Nondiscrimination on the basis of handicap; procedures and guidelines relating to health care for handicapped infants. HHS Final Rules, *Fed Regist* **50** (1985), 14879–14892.

[10] US Child Abuse Prevention and Treatment Act, Pub L, No. 42 USC 5101 *et seq*.

[11] US Rehabilitation Act, Pub L, No. 93-112, 29 USC 794.

[12] *Bowen v. American Hospital Association*, 476 US 610 (1986).

[13] American Academy of Pediatrics, Committee on Bioethics. Ethics and the care of critically ill infants and children, *Pediatrics* **98** (1996), 149–153.

[14] L.M. Kopelman, T.G. Irons and A.E. Kopelman, Neonatologists judge the Baby Doe regulations, *New Engl J Med* **318** (1988), 677–683.

[15] *Montalvo v. Borkovec*, 2002 WI App. 147, 256 Wis. 2d 472, 647 N.W.2d 413 (2002), *pet. review den*. 2002 WI 121 (2002), *pet cert. den*. 538 US 907 (2003).

[16] *Miller v. HCA*, 47 Tex. Sup. J. 12, 118 S.W.3d 758 (2003).

[17] L.M. Kopelman, Baby Doe Rules (letter), *Pediatrics* **116** (2005), 1602–1603.

[18] 45 CFR § 1340.15.

[19] K. Costeloe, E. Hennessy, A.T. Gibson, N. Marlow and A.R. Wilkinson, The EPICure study: Outcomes to discharge from hospital for infants born at the threshold of viability, *Pediatrics* **106** (2000), 659–671.

[20] N.S. Wood, N. Marlow, K. Costeloe, A.T. Gibson and A.R. Wilkinson, Neurologic and developmental disability after extremely preterm birth, *New Engl J Med* **343** (2000), 378–384.

[21] N. Marlow, D. Wolke, M.A. Bracewell and M. Samara. Neurologic and developmental disability at six years of age after extremely preterm birth, *New Engl J Med* **352** (2005), 9–19.

[22] S. Kusuda, M. Fujimura, I. Sakuma, H. Aotani, K. Kabe, Y. Itani et al., Morbidity and mortality of infants with very low birth weight in Japan: Center variation, *Pediatrics* **118** (2006), e1130–e1138.

[23] J. F. Lucey, C.A. Rowan, P.Shiono, A.R. Wilkinson, S. Kilpatrick, N.R. Payne et al., Fetal infants: The fate of 4172 infants with birth weights of 401–500 grams – The Vermont Oxford Network experience, *Pediatrics* **113** (2004), 1559–1566.

[24] I. Seri and J. Evans, Limits of viability: Definition of the gray zone, *J Perinatology* **28** (2008), S4–S8.

[25] J.D. Lantos, *The Lazarus Case: Life and Death Issues in Neonatal Intensive Care*. The Johns Hopkins University Press, 2001, 79–80.

[26] B.R. Vohr and M. Allen, Extreme prematurity: The continuing dilemma, *New Engl J Med* **352** (2005), 71–72.

[27] L. Frain and Y. Ren, Certainty, uncertainty, and accuracy of daily predictions of non- survival in the NICU: We're often wrong but rarely in doubt, *Pediatric Research* **43** (1998), 29A.

[28] International Liaison Committee on Resuscitation (European Resuscitation Council & American Heart Association). Neonatal resuscitation, *Resuscitation* **67** (2005), 293–303.

[29] S.V. McCrary, J.W. Swanson, H.S. Perkins and W.J. Winslade. Treatment decisions for terminally ill patients: Physicians' legal defensiveness and knowledge of medical law, *Law, Med & Health Care* **20** (1992), 364–376.

[30] J.W. Swanson and S.V. McCrary, Medical futility decisions and physicians' legal defensiveness: The impact of anticipated

[2] New York State Bar Association and Medical Society of the State of New York, *Legal Manual for New York Physicians* (New York: New York State Bar Association, 2003), 337.

conflict on thresholds for end-of-life treatment, *Social Sci & Med* **42** (1996), 125–132.
[31] J.W. Swanson and S.V. McCrary. Doing all they can: Physicians who deny medical futility, *J Law, Med & Ethics* **22** (1994), 318–326.
[32] S.V. McCrary and J.W. Swanson, Physicians' Legal Defensiveness and Knowledge of Medical Law: Comparing Denmark and the USA, *Scandinavian J Pub Health* **27** (1999), 18–21.
[33] S.V. McCrary, J.W. Swanson, J. Coulehan, K. Faber-Langendoen, R.S. Olick and C. Belling, Physicians' legal defensiveness in end-of-life treatment decisions: Comparing attitudes and knowledge in states with different laws, *J Clin Ethics* **17** (2006), 15–26.
[34] *In re Westchester County Medical Center ex rel. O'Connor*, 72 N.Y.2d 517, 534 N.Y.S.2d 886, 531 N.E.2d 607 (1988).
[35] S.V. McCrary, *Dwelling in the Shadow: Physicians' Decision Making for Terminally Ill Patients*, Doctoral dissertation, University of Texas Medical Branch, 1992, 67.
[36] S. Toulmin, Medical institutions and their moral constraints, in: *Integrity in Health Care Institutions*, R.E. Bulger and S.J. Reiser, eds, Iowa City: University of Iowa Press, 1990, pp. 26–27.