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NEW TECHNOLOGY, NEW LAW: STEM CELL PRODUCTS*

Stephen R. Munzer

New technologies do not always require new legal arrangements. But new stem cell products pose different risks, and may offer different rewards, from other drugs, biologics, and combination products.¹ This new technology does require new law.

I. INTRODUCTION

In fact, it requires new law in two separate but related areas. One is product liability law, which is part of the law of torts. The other is administrative law, which would enable the Food and Drug Administration (“FDA”) to offer new regulations to deal with the special features of stem cell products.

In 2012 I published two articles that had started out as a single obscenely long draft.² I had to split the draft into different articles. One article offered a proposal for tort law applicable to stem cell products. The other suggested a proposal for the administrative law that should govern the FDA’s oversight of stem cell products. Splitting a lengthy draft in two was easy. The hard part was showing how the two proposals fit together in the right way.

This essay spends no time carping about the deficiencies of existing law or the suggestions of other scholars. It spills just enough ink on the two proposals to make their content and justification clear. The chief contribution of this essay is to show how these proposals are integrated in the most useful way, and it is that contribution that receives the most attention here. In my view, the interlocking tort and regulatory elements must satisfy three criteria: complementarity, well-suitedness, and mutual reinforcement. These are semi-technical terms, and I will explain them in due course. The bulk of this essay, then, concerns how these proposals meet the criteria just mentioned.

Broadly, a stem cell is any cell that has the capacity to self-renew and to differentiate into a more committed cell. The most basic stem cell is a zygote—the product of fertilization of an egg by a sperm cell. As the cells

II. STEM CELL PRODUCTS

of the organism divide, the zygote becomes a blastocyst, then an embryo, and eventually a fetus. Nonhuman animals have stem cells too, but here I am concerned only with human stem cells. These fall into two main categories.

The first are tissue-specific stem cells. Of these the most conspicuous examples are hematopoietic (blood forming) stem cells, which can be obtained from bone marrow, umbilical cord blood, and with much more difficulty from circulating adult blood. Tissue-specific stem cells have been in use for some while to treat blood cancers and some anemias. In fact, the only stem cell products specifically approved by the FDA are tissue-specific stem cells and stem cell lines.³

The other category of stem cells consists of human embryonic stem cells (“hESCs”) and human induced pluripotent stem cells (“hiPSCs”). Cells in this second category hold great promise in treating disease and in regenerative medicine generally because in principle they can be coaxed to differentiate into any other kind of cell in the human body. Unfortunately, cells in this category pose much more in the way of risks, both known and unknown. For instance, some such cells may cause cancers.

There is much hoopla about stem cell research. At this point, I doubt that all the hype is justified. But I am not a naysayer either. I am a realist who seeks to have adequate safeguards, in both tort and administrative law, for the responsible development and exploitation of stem cell products to be used in regenerative medicine. Articulating these legal safeguards is a job for today, not for a decade later when legal and policy analysts can do little more than play catch-up.

III. LITIGATION OVER STEM CELL PRODUCTS

Although the FDA has asserted jurisdiction over stem cell products and what some authors call stem cell treatments for two decades,⁴ the matter is in litigation pending a possible appeal, and later cases may raise similar issues. Regenerative Sciences, LLC (“Regenerative Sciences”) sued the FDA to prevent the federal agency from interfering with its activities.⁵ Regenerative Sciences is a Colorado firm that isolates mesenchymal stem cells (“MSCs”) from bone marrow. It then cultures the cells, adds some materials, and uses the mix for injection into patients. Its main treatment is called “Regenexx-C”; the “C” stands for “Cultured.”⁶ In 2008, the FDA sent a warning “letter to Regenerative Sciences stating that, based on the way the use of MSCs was being promoted on the Regenexx website, it considered those cells to be drugs and biological products” over which the FDA had authority.⁷

The company’s position was that its MSCs were not drugs or biologics and that the

FDA was interfering with the practice of medicine. Eventually the company sued the FDA for injunctive and declaratory relief. A federal district court granted the FDA's motion to dismiss on ripeness grounds because the FDA had not yet attempted to regulate Regenerative Sciences.⁸ In June 2010, Regenerative Sciences "applied for an order 'to prompt the FDA to take "final agency action" or leave its medical practice alone'."⁹ Later, the FDA sought an injunction and ultimately, in January 2011, moved for summary judgment and dismissal of the defendants' counterclaims.¹⁰

In the newly captioned *United States v. Regenerative Sciences, LLC*,¹¹ the court ruled in favor of the United States and granted its request for a permanent injunction against the defendants. The court said that "the cell product used in the Regenexx™ Procedure meets the statutory definition for both a 'drug' under the FFDC [Federal Food, Drug, and Cosmetics Act] and a 'biological product' under the PHSA [Public Health Service Act]."¹² The court then concluded that Regenerative Sciences' cultured mesenchymal stem cell products amount to a "drug" under federal law.¹³ One might cavil whether Regenerative Sciences' MSCs are better classified as a biological product, or as both a drug and a biological product. In any event, the thrust of the decision is sound because of the amount of manipulation the MSCs received and because of the need to control inadequately vetted stem cell products.

This case is interesting partly because of its political valence. The protests of Regenerative Sciences prior to the injunction had become a rallying cry against FDA regulation. Two articles addressed this litigation while it was in progress. One acknowledged that Regenerative Sciences was likely to lose but contended that "the FDA should recognize that it makes little sense to impose a regulatory framework developed for mass manufacturers on small physician practices."¹⁴ The majority shareholders of Regenerative Sciences are two physicians who operate a clinic in Broomfield, Colorado, where, prior to the injunction, they injected Regenexx-C into patients.¹⁵

But the crucial point is not the size of the laboratory or manufacturer. What's crucial is the nature and degree of the manipulation of the components of Regenexx-C. To create this product, MSCs are harvested from the patient's hip. The patient's blood is then drawn to isolate growth factors. Finally, using the MSCs, growth factors, reagents, and culture media, Regenerative Sciences increases the number of MSCs that go into Regenexx-C.¹⁶ The manipulation of these ingredients is sufficiently intensive to warrant FDA oversight. This is not a case of regulation run wild.

Barbara von Tigerstrom, a well-known writer on stem cell technology and tissue engineering, was the author of the other article on this litigation while it was in progress. She makes a strong case that the FDA's regulation in this situation is

“eminently reasonable.”¹⁷ It would be even more reasonable in cases involving allogeneic, rather than autologous,¹⁸ stem cell products and treatments, and in cases using autologous human induced pluripotent stem cells, or “hiPSCs.”¹⁹ Regulation is also needed to thwart stem cell tourism, whether within or outside the United States, because insufficiently vetted stem cell products pose health risks no matter where the products are administered.²⁰

IV. A PROPOSED TORT LIABILITY REGIME FOR STEM CELL PRODUCTS

The tort structure I propose mandates strict liability for products with inadequate warnings or defects, yet adopts measures to safeguard product development and thus encourage innovation. Thus, my product liability proposal contains significant qualifications. These secure a balance among innovation, safety, effectiveness, and patient preferences. This balance is informed by the ethics of imposing risks²¹ on others as well as by economic theory. My proposal is mindful of the difficulty in determining the causes of harm in the design, development, manufacture, and use of stem cell products.

A. Why Strict Liability Needs to be Qualified

To begin, a strict liability scheme should include a socialized insurance function to hold down the financial burden on pioneers in the field. Money for a socialized insurance fund would come from patients, designers, and manufacturers. The government would act as an insurer of last resort.

One could arrange contributions to the fund in various ways. Perhaps the most straightforward arrangement would have patients pay into the fund for each treatment and firms pay into the fund for each stem cell product. In this scheme, for every stem cell product a firm manufactures, it would pay a fixed amount into the insurance fund. These payments from various sources would defray the costs of caring for those patients who have adverse reactions to stem cell products.

The point of my socialized insurance scheme is to spread the cost of liability, but my product liability proposal has additional rules to suppress some of the undesirable effects of an unqualified strict liability regime. These include an unavoidably unsafe rule, a learned intermediary rule, FDA approval as a rebuttable presumption in defective design suits, a state-of-the-art defense, a collateral-source rule, and assorted limitations on damages, especially on punitive damages.

My tort proposal also includes an exception for compassionate use of stem cell products to encourage a balance between patient safety and patient preferences. Patients who are diagnosed with serious or terminal conditions that lack suitable non-stem cell treatments might want to be treated with cutting edge stem cell

products. In such cases, firms should not be held liable for the harms these products cause, even though the stem cell products at issue may be insufficiently tested to warrant putting them on the market generally.

Because informed consent is vital to the ethics of imposing risk on patients, I would allow the compassionate use of insufficiently tested stem cell products only when patients were informed of the risks of such use and discouraged from taking inordinate risks.²² Even then, I would permit use of these products only in serious cases.

The FDA, the patient, and the treating physician should have the main voices in deciding whether a condition is serious enough to warrant a compassionate-use exception. They should also have the main voices in deciding whether safer treatments are insufficiently effective to merit the use of a less well-tested stem cell product.

Still, one must be wary of a slippery slope in such decisions. Suppose that an existing treatment is safe and effective—but also very expensive. I doubt that an insufficiently tested but cheaper stem cell alternative treatment should be allowed on grounds of compassionate use. We should avoid the risk of a secondary market developing for stem cell products in which manufacturers both avoid product liability and market these products to patients who are less well off financially and less well informed than most patients.

If a stem cell product causes harm, pinpointing the exact cause of that harm can be a serious challenge. First, a stem cell product may become defective at various points in its development. The design may be faulty, the stem cell line may be corrupted, or the manufacture may be shoddy. Next, the product might cause harm when administered to the patient. For instance, medical personnel may improperly dispense or store the product, and thereby create or even compound the harm. Further, these scenarios, and many more besides, could combine to produce the harm that results. Unearthing the likely cause of any particular harm may be especially difficult with stem cell products because the use, design, manufacture, and development of these products will be novel. Interplay among these possibilities might aggravate the task of identifying the causes of the harm a patient suffers.

For these reasons, my qualified strict liability scheme explores collective and proportional liability theories.²³ Under these theories, plaintiffs would be allowed to recover damages against multiple members of the supply chain in situations where

**B. Apportioning
Liability in the
Supply Chain
Under a Strict
Liability Scheme**

fault cannot be satisfactorily shown as to any one party. Proportional liability would parcel out the cost of liability based on the degree of harm each of the defendants caused. Members of the supply chain would be free to allocate the costs of liability among themselves, such as through indemnification arrangements. They could also reduce their collective risk through self-regulation.

In at least three cases, the party responsible for the harm may be uniquely identifiable. For instance, if a design is faulty, the plaintiff may bring suit against the design firm. Likewise, depending on the harm, a lawsuit may be brought for a manufacturing defect against the manufacturer or for an inadequate warning against either the manufacturer or designer. Each type of lawsuit presents distinct challenges.²⁴

As to the first case, a defect in design may create liability if there were safer design alternatives available at the time the product was conceived. If no such design existed, designers ought to be able to avoid liability with the state-of-the-art defense.

The second case—suing the manufacturer—would be potentially more lucrative for plaintiffs since manufacturers would rarely have a state-of-the-art defense.

In regard to the third case, a lawsuit for inadequate warnings should fail in most cases if the warnings were transparent, but such warnings could increase the potential liability for designers and manufacturers, and thus reduce their incentive to unearth adverse information. To avoid this result, courts could create protections for early warnings, but afford no such protections for delayed warnings.

**V. A NEW
REGULATORY
PROPOSAL**

**A. The Core of
the Proposal**

Because so much uncertainty surrounds the risks associated with stem cell products, the FDA should play a more aggressive role than usual in deciding which of these products should be allowed on the market and what instructions, warnings, and restrictions on use should be applied.

The FDA should concentrate above all on safety risks and risks of ineffectiveness. As to safety, the FDA ought to refuse to allow the marketing of any stem cell products whose risks are deemed unacceptable for virtually all patients. In regard to effectiveness, it should not allow ineffective products at all and should permit marginally effective stem cell products only if no other treatments are available and the products pose little in the way of safety risks.

The FDA center that should take the lead in evaluating stem cell products, as well as their risks and effectiveness, is the Center for Biologic Evaluation and Research

("CBER"). It has the best track record in dealing with biologically active materials. If a stem cell product is harnessed to a delivery device, the Office of Combination Products ("OCP") should step in. Even here CBER, not the OCP, should have the dominant role.

1. Strengthening Pre-Approval Requirements and Pre-Clinical Administrative Review

B. Some Details
of the Regulatory
Proposal

The best antidotes for inadequate information are more and better information. In light of better information, the FDA should consider strengthening its pre-approval requirements and pre-clinical regulatory review. It can do so by tamping down on accelerated or fast-track review, and developing standards for testing and approving stem cell products.

2. Post-Market Regulation

Few lapses are as well documented as problems with the FDA's post-market drug-safety program. One has only to utter the name Vioxx. In the case of stem cell products, the FDA should require physicians and manufacturers to report adverse events promptly. It should also articulate clear, effective, and objective criteria and processes for which actions to take when adverse events become known. Once again, CBER is likely to be the best FDA center to carry out these actions.

3. Risk-Management and Risk-Reduction System

CBER should consider designing and managing a database that includes information on adverse events and protocols for managing the risks. The data should be accessible by physicians, patients, research scientists, designers and manufacturers of stem cell products, and health insurers. These groups have different informational needs, and the material in the database will not be equally usable by everyone.

Voluntary organizations, such as the American Cancer Society, may be able to enrich CBER's database. Their help ought not to be refused.

Any system of this sort will have cons and pros. Among the disadvantages are the costs of setting up and maintaining the database. Also, scientists and manufacturers have legitimate concerns about their patents, patent applications in progress, and proprietary information generally. The principal advantages, which I think outweigh the cons, lie in fostering the safety and effectiveness of stem cell products and the decisions to use or avoid them. Physicians and patients can work together on the

best treatment options. Health insurers can make informed decisions on which products merit coverage.

4. Relation to Product Liability

If the regulatory proposal is put in place, that should have some impact on manufacturers' liability for defective stem cell products if only because manufacturers have to jump through more hoops. If the level and degree of regulation of a stem cell product are fairly and accurately adjusted to match its safety risks and its relative effectiveness, that might reduce manufacturers' liability in products suits. Sometimes increased protection should be received by manufacturers, but only if they meet all reporting requirements for post-market evidence of adverse events or ineffectiveness.

VI. INTEGRATING ADMINISTRATIVE AND PRODUCT LIABILITY LAW

Accepting my administrative proposal does not require acceptance of my product liability proposal, nor does accepting my product liability proposal require acceptance of my administrative proposal. However, the two proposals are consistent with each other. Moreover, they are complementary, well-suited to each other, and mutually reinforcing. As to integration, the nub of the matter is to clearly specify *how* they interact on these criteria.

A. How the Two Proposals Mesh with Each Other

Stem cell products have risks that are largely unknown and potential rewards that are highly touted. The tort and administrative proposals summarized in this essay share some aims and means for reducing the risks of stem cell products while permitting their relatively unencumbered development. To explain how the commonalities between these proposals enable them to mesh well together, it is necessary to clarify three key terms, which I use in a semi-technical way.

Two proposals are *complementary* if they work together to promote common aims.

Two proposals are *well-suited* if they use the same or similar means to achieve their shared aims with as little waste as possible of resources expended on extraneous means and aims.

Finally, two proposals are *mutually reinforcing* if each encourages compliance with the other.

Take note that writing of aims, means, incentives, and avoiding waste does not make either proposal, or both of them together, a wholly consequentialist affair. The best analyses of risk reduction, risk management, and risk imposition have an important

non-consequentialist cog in that they take seriously the ethics of imposing risks on other people.²⁵

The proposals advanced here share the following aims: mitigating disincentives to enter the stem cell market; increasing the safety of stem cell products and thereby lowering the risks they pose to consumers; and promoting the effectiveness of stem cell products and thereby increasing their usefulness to consumers.

1. *Entry*

The product liability proposal mitigates disincentives to enter the stem cell market. It thereby advances safety in two ways. First, it immunizes firms that disclose post-market test results from liability in inadequate warning lawsuits. The disclosure must be timely, but such prompt notice enables designers and manufacturers to limit liability, which offers the prospect of increased profits. Second, the proposal limits punitive damages for firms that have fully complied with all FDA requirements. This limitation reduces the monetary risks of designing and making stem cell products. Lowering the exposure to one category of damages should draw more firms into the market. It should also increase the quality and variety of stem cell products, which might help control prices for consumers. Thus, limiting liability and in turn reducing barriers to entry increase the incentive to disclose post-market test results and to comply fully with all FDA requirements that advance safety.

The administrative proposal also mitigates disincentives to enter the stem cell market in various ways and thereby promotes safety. To begin, it eliminates the lobbying that would otherwise be needed to slot a proposed stem cell product into a particular FDA center. Under current law, firms often hire lawyers or professional lobbyists to persuade the FDA to place their products into a center that tests, or at least is believed to test, less rigorously and less expensively than another center. The proposal eliminates this lobbying expense by having a single department within CBER evaluate all proposed stem cell products.

Some might contend that the mandatory insurance provision in the product liability proposal will greatly increase barriers to entry and thereby raise prices to consumers. However, this assertion is easily rebutted. All insurance costs something. If it did not, there would be no reason for the insurer to provide any coverage. For designers and manufacturers of stem cell products, buying insurance is a way to hedge against risk. Hence, a required insurance premium, while possibly representing a minor barrier to entry, provides an even greater demonstrable benefit that reinforces the complementary nature of the product liability and administrative proposals. The mandatory insurance provision thus serves to mitigate disincentives to enter the stem cell market.

Further, the mandatory insurance premium is based partly on market share. Thus, a firm hoping to break into the field will face relatively small insurance costs. In return for a modest premium, the firm cabins the risk of debilitating judgments and settlements. Thereafter, efforts to improve safety and effectiveness, the eventual success of those efforts, compliance with post-market regulations, and the securing of FDA approval will all play a role in decreasing firms' payments into the mandatory insurance fund. As with all insurance, the premium paid hedges against risk, and that hedge should appeal to almost all firms, large and small. Consequently, the mandatory insurance provision does not prevent the two proposals from mitigating disincentives to enter this market. As a result, any effect on costs to consumers stemming from the mandatory insurance provision is likely to be modest.

2. *Safety*

The two proposals are also complementary because they work together to increase the safety of stem cell products and thereby decrease the risks to consumers. The product liability proposal advances this end by incentivizing firms to follow FDA procedures that will likely make their products safer by limiting liability and punitive damages in exchange for compliance. Further, FDA approval of products results in a rebuttable presumption of safety so far as design flaws are concerned. The availability of this presumption should encourage firms to comply with FDA regulations. As a corollary, compliance with FDA regulations might lead to a reduction in the insurance premiums paid by firms.

The administrative proposal seeks to increase the safety of stem cell products through its risk-reduction and risk-management system. This system provides for the rapid dissemination of information among firms, doctors, patients, consumers, and the FDA. The heightened level and quality of information should enable all concerned to make better choices about the design, manufacture, and use of stem cell products. In this situation, better choices include safer choices.

Two primary objections exist to the argument for complementarity. The first is that various parts of the product liability proposal actually increase risk to consumers. Limits on punitive damages might lead to carelessness on the part of designers and manufacturers. Immunizing defendants in failure-to-warn suits because of timely disclosure of post-market test results lowers the deterrent value of product liability suits. This lower value in turn decreases consumers' prospects of financial recovery. The objection, if sound, might suggest that the product liability proposal is not complementary to the administrative proposal, as the former undermines the aim of decreasing risk to consumers.

However, analysis of this objection reveals that it has less weight than it initially appears. For a start, the objection relies on a suppressed premise—namely, that many, if not most, parts of the product liability proposal increase consumer risk. Without this premise as a base, to be convincing the objection requires extrapolation from the few parts mentioned in the preceding paragraph to all or most parts of this proposal. Such an extrapolation is patently unwarranted, for it is evident that the proposal contains many provisions that increase consumer safety. Among them are tort liability for defective products and inadequate warnings and the fact that the regime suggested is a modified strict liability regime for stem cell products. Precisely because the extrapolation is unwarranted and the suppressed premise is false, many, if not most, parts of the proposal advance consumer safety.

A further point has to do with the part-to-whole relationship contemplated by the first objection. One way of putting the objection is that some elements of the product liability proposal undermine safety, or at least seem to do so. This is the “part.” From this point, the objector reasons that the proposal overall undermines safety. This is the “whole.” This reasoning is fallacious. What is true of a part, or even of several parts, need not be true of the whole. It could well be that the proposal overall advances safety. So it is not simply that the suppressed premise is false and the extrapolation is unwarranted that the proposal advances safety; it is *because* the suppressed premise is false and the extrapolation is fallacious that the overall proposal could advance safety.

Moreover, both proposals seek to take competing considerations into account. On the one hand, were safety standards raised to an unattainable level, fewer firms would place even a toe in the icy waters of the market. On the other hand, were regulations decreased or loosened and tort actions curtailed, the prospect would arise of a free-for-all market in which firms cut costs and put out substandard products. Although some balancing is in order, it is ham-handed to turn the entire conversation into “weighing” things on “scales.” A virtue of much sophisticated work in moral and political theory is the move away from sole reliance on crude balancing metaphors to a wider awareness of the ways in which reasons and normative considerations on one side can variously exclude, undercut, override, neutralize, or otherwise affect reasons and normative considerations on the other.²⁶

At the intersection of the two proposals, then, we must be wary certainly of tipping the scale too far in either direction. But we must be equally wary of allowing one proposal to exclude, or otherwise undercut the other to an indefensible extent. Once these points are taken to heart, we see that the liability proposal must not be pushed so far as to throw the administrative proposal out of balance or to derail it. The parts of the liability proposal that the objection invokes fall well short of an

exhaustive list of its parts. Other parts provide a good many incentives to safety. Consequently, once a judicious merger of Parts IV and V is reached, the fact that some aspects of the product liability proposal might result in less than sharply reduced consumer risk does not defeat the complementarity of the proposals with respect to safety.

So much for the first objection. The second objection is that the various incentives to follow FDA procedures, in the hope of avoiding product liability or at least punitive damages, might not increase consumer safety. The claim that it increases safety, the objection goes, depends on the idea that the FDA has special knowledge about stem cell products. Only with this special knowledge can the FDA assess accurately the safety of products submitted for its approval. Yet, the objection concludes, right now the FDA has no such expertise or special knowledge.

This objection raises a problem that the administrative proposal is designed to overcome or at least to limit. It will take some time for the new department within CBER to gain great knowledge of stem cell products. But it will likely not take long, for in the past two decades graduate schools in the life sciences have been minting new scientists with doctorates in stem cell biology. Hence, there should be a good labor supply of qualified scientists.

Moreover, the proposal deals with the timing issue by instituting various requirements that must be met before the limit on punitive damages takes effect. One such requirement is that the FDA have a more accurate picture of the risks of stem cell products. So before the limits on product liability damages come into effect, stem cell technology must be well enough studied for the FDA, designers, manufacturers, physicians, and consumers to have a decent grasp of the risks. In consequence, the objective of consumer safety has priority over mitigating the disincentives to enter the market.

Hence, when the incentives to follow FDA procedures do take effect, the specialized knowledge of the FDA will enable compliance with the FDA procedures to increase consumer safety. Granted, this point does not entail that safety will increase immediately. Still, the modest limits on liability, preclusion of punitive damages, and significant barriers to entry are likely to have two further effects. One is to encourage independent safety protocols by manufacturers and regulators. The other is to give the FDA time to come up with well-vetted procedures for increasing safety.

3. Effectiveness

Here the product liability proposal plays a minor role, for consumers can hardly sue in tort just because a particular stem cell product failed to help them. Still, consumers might be able to sue manufacturers for false or misleading advertising. Also, the regime of modified strict liability encourages designers and manufacturers to avoid unnecessary risks and to produce products that work well. In these ways, the tort proposal thus furthers effectiveness to some extent.

The administrative proposal pulls the laboring oar for effectiveness. Under it, the FDA will approve only products that clinical trials have shown to be effective for a given injury, disease, or condition. Additionally, if post-market testing indicates that certain products are ineffective, or are less effective than alternatives that have better-known risk profiles, then ineffective products will be withdrawn from the market, and less effective products with decent alternatives will decline in market share. Thus, the two proposals are complementary not only with respect to safety and mitigating disincentives to enter the stem cell market but also with respect to effectiveness.

Complementarity has to do with ends; well-suitedness concerns means. Recall that two proposals are well-suited if they use the same or similar means to achieve their shared ends with as little waste as possible of resources expended on extraneous means and ends. Two features of my proposals illustrate how well-suited they are to each other. The risk-management system created for the FDA is used in product liability cases. And the prompt disclosure of post-market test results both brings stem cell products into compliance with suggested FDA regulations and shields against some sorts of product liability lawsuits.

C. Well-Suitedness
and Common
Means

1. Risk-Management System

The system advocated in the administrative proposal includes a database of stem cell products that contains, among other things, information on their safety and effectiveness. The contents of the database include information secured by post-market testing. By having this information readily accessible, the database makes it easier to determine the insurance premiums to be paid for various stem cell products in light of their claims histories. From the database, the entity overseeing the product liability insurance fund has an easier road to determine the market share of various firms.

Thus, both proposals employ the same or similar means to further the aims of safety and effectiveness. These means might also advance the aim of mitigating disincentives to enter the stem cell market by calibrating mitigation. The two

proposals are well suited to each other, for the database included in the risk-management system aids both the administrative and product liability schemes in achieving their similar objectives.

2. *Disclosing Post-Market Test Results*

The product liability proposal uses incentives for firms to disclose post-market test results even when, and especially when, they are unfavorable to the firms' products. The administrative proposal compels such disclosure. Here, similar means advance the ends of having safe and effective stem cell products.

Precisely how the two proposals interlock here is slightly complicated. Insofar as the FDA has the legal authority to compel the disclosure of post-market test results, backfiring can occur. To combat the possibility of backfire—having less information rather than more as a result of regulation—the qualified strict liability regime limits the information that plaintiffs can use in inadequate-warning suits. The product liability proposal would also limit punitive damages. Hence this proposal has ways to encourage speedy disclosure by firms of post-market test results. The two proposals are well suited in that both use similar means to advance the ends of safety and effectiveness.

Let no one contend that a combination of carrot, via the product liability proposal, and stick, via the administrative proposal, is unnecessary. The idea behind such a contention seems to be that incentivizing something while also compelling it is exactly what makes the two proposals ill suited, or, at least, redundant.

I reply that here we need both carrot and stick. With only the stick, firms might well cease, or curtail, post-market testing for fear of product liability. With only the carrot, some firms might choose not to comply with the FDA. Noncompliance might be the result of calculating either that the costs of disclosure outweigh the benefits or that the unfavorable information is unlikely to be discovered by anyone else. Either way, the consumer is left at a higher risk of using an unsafe or ineffective product. What may seem superfluous is in fact necessary. The two proposals should use the common means of disclosure to pursue ends of safety and effectiveness.

D. Mutual Reinforcement

Two proposals are mutually reinforcing if each encourages compliance with the other. We have already seen one instance of mutual reinforcement: disclosure of post-market testing as mandated by the FDA reinforces—and is reinforced by—the corresponding immunity given in product liability litigation. Here are three more examples.

1. *Rebuttable Presumption of Safety*

Under the administrative proposal, FDA approval gives designers a rebuttable presumption of safety in product liability suits. The product liability proposal, by giving designers some protection against strict liability, spurs them to comply with FDA regulations for approving a stem cell product. Further, the rebuttable presumption of safety is bolstered by, and partly justified on the basis of, stricter FDA approval standards that increase consumer safety. Thus the added difficulty in securing FDA approval should erase doubts that the presumption might compromise consumer safety.

2. *Limits on Punitive Damages*

The punitive damages limit and compliance with the suggested FDA regulatory scheme mutually reinforce each other. The product liability regime, by limiting firm exposure to punitive damages, offers an incentive for firms to adhere to FDA regulations. In turn, strict FDA regulations are warranted partly because compliance with them limits the damages that injured plaintiffs can recover.

3. *Risk Management and Socialized Insurance*

The administrative proposal includes a risk-management system. This system, with its database, facilitates the exchange of information among the FDA, designers, manufacturers, physicians, and patients. The transparency of the system gives firms an incentive to participate honestly. The product liability proposal includes a socialized insurance scheme. Firms' premiums are partly a function of information about the safety and effectiveness of their products. Honest participation in the risk-management system is likely to hold down the amount of their insurance premiums. Consequently, the socialized insurance scheme provides incentives to participate honestly in the risk-management system and to comply with FDA regulations pertaining to safety and effectiveness.

Only Pollyanna, some might say, would have such an optimistic view of the honesty of designers and manufacturers.²⁷ They are likely, some would say, to provide *false* information. To a significant extent, I disagree. By no means am I blessed with the constant sincerity and sunny disposition of the title character in Porter's novel. Yet I think that the penalties for false statements by designers and manufacturers, aided by the transparency of the system in which they work, are apt to induce honest participation and significant, if grudging, compliance with FDA regulations.

The whole of the mutual reinforcement argument can be seen by looking at the above examples in the aggregate. The prospect of having to pay large judgments

or settlements in a stem cell product liability suit may lead even the most safety-conscious firms to think twice about entering the stem cell market. By encouraging compliance with strict FDA regulations, the two proposals work together to increase safety and lower the chance that firms will be hit by an enormous verdict despite meticulous research and development. The rebuttable presumption of safety that arises from FDA approval further lowers the chances that firms will be exposed to substantial liability. The limit on punitive damages resulting from compliance with FDA procedures protects firms against debilitating damage awards even if a verdict is returned against it. Conversely, the socialized insurance premiums reflect, in their amounts, regulatory compliance. Should all firms comply with FDA regulations, it becomes even more appropriate that socialized insurance ought to exist to prevent any one firm from financial ruin.

To sum up: these examples, as components of proposals for two different areas of the law, show that the proposals mutually reinforce each other in encouraging increased safety and effectiveness pursuant to FDA regulations by way of limiting potential liability and mitigating disincentives to market entry.

CONCLUSION

The possibilities of stem cell products in treating disease and in regenerative medicine are vast. These possibilities, though, come with significant risks. It would be regrettable to delay the needed reformation of administrative law until hundreds, if not thousands, of stem cell products are on the market. The administrative regulation of eventual stem cell products by the FDA will require exacting attention to safety and effectiveness without imposing an undue burden on manufacturers. The same is true for product liability claims regarding stem cell products.

Alas, no existing category—whether vaccines or blood products or combination products—offers a perfect legal model for stem cell products. However, one can tease out pertinent features of these categories to show what might work well for stem cell products. These features can then be considered and molded into more definitive recommendations as these products appear on the market and their risks and rewards become better understood over the coming decades. The proposals advanced here therefore have a dynamic quality that allows for adaptations as superior information becomes available.

- * Stephen Munzer is Distinguished Professor of Law at UCLA School of Law. I am most grateful for the help of Karen Y. Lam, Robert Lawner, Mark Metzke, Jamie L. Summers, Jenifer Wiseman, and Douglas Wolfe. This article is an abridged version of Stephen R. Munzer, *How to Integrate Administrative Law and Tort Law: The Regulation of Stem Cell Products*, 64 ADMIN. L. REV. 743 (2012); Stephen R. Munzer, *Risk and Reward in Stem Cell Products: A New Model for Stem Cell Product Liability*, 18 B.U. J. SCI. & TECH. L. 102 (2012).
1. Some authors speak of “treatments” and others of “products.” The Food and Drug Administration has asserted jurisdiction over both. Throughout I use the term stem cell “products.”
 2. Stephen R. Munzer, *How to Integrate Administrative Law and Tort Law: The Regulation of Stem Cell Products*, 64 ADMIN. L. REV. 743 (2012); Stephen R. Munzer, *Risk and Reward in Stem Cell Products: A New Model for Stem Cell Product Liability*, 18 B.U. J. SCI. & TECH. L. 102 (2012) [hereinafter Munzer, *Risk and Reward*].
 3. The FDA approved a stem cell product known as Hemacord on November 10, 2011. *November 10, 2011 Approval Letter—Hemacord*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm279613.htm> (last updated Nov. 10, 2011). Anyone who clicks on the Package Insert for Hemacord on the FDA website above will see that the warnings are substantial. Less than a year later, the FDA approved another stem cell product. *See May 24, 2012 Approval Letter—HPC, Cord Blood*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/ucm305620.htm?utm> (last updated May 25, 2012) (approving HPC, cord blood). Canada has approved Prochymal, a mesenchymal stem cell product used to treat children with graft-versus-host disease and perhaps other ailments. *See also* Andrew Pollack, *A Stem-Cell-Based Drug Gets Approval in Canada*, N.Y. TIMES, May 17, 2012, <http://www.nytimes.com/2012/05/18/health/a-stem-cell-based-drug-gets-approval-in-canada.html>.
 4. Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products, 58 Fed. Reg. 53,248–51 (1993). *See also* United States v. Loran Med. Sys., Inc., 25 F. Supp. 2d 1082 (C.D. Cal. 1997) (issuing a permanent injunction on the importation of neonatal cells); CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: GUIDANCE FOR HUMAN SOMATIC CELL THERAPY AND GENE THERAPY 3 (Mar. 1998), available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/ucm081670.pdf>; Donald W. Fink et al., *FDA Regulation of Stem Cell-Based Products*, 324 SCIENCE 1662 (2009). For use of the term “stem cell treatments,” see RUSSELL KOROBKIN, *STEM CELL CENTURY: LAW AND POLICY FOR A BREAKTHROUGH TECHNOLOGY* 232–57 (2007). Korobkin believes that the FDA has “the authority to regulate premarket approval of stem cell treatments,” but adds, correctly, that “[w]hether and when the FDA should exercise this authority is a different question.” *Id.* at 243.

5. Regenerative Sciences, Inc. v. U.S. Food & Drug Admin., No. 09-CV-00411-WYD-BNB, 2010 WL 1258010 (D. Colo. Mar. 26, 2010). The company sometimes drops “LLC” and calls itself Regenerative Sciences, Inc.
6. *Regenexx Procedures Family—Stem Cell and Platelet Procedures*, REGENEXX, <http://www.regenexx.com/regenexx-procedures-family/> (last visited Nov. 9, 2012).
7. Barbara von Tigerstrom, *The Food and Drug Administration, Regenerative Sciences, and the Regulation of Autologous Stem Cell Therapies*, 66 FOOD & DRUG L.J. 479, 482 (2011).
8. Regenerative Sciences, Inc. v. U.S. Food & Drug Admin., No. 09-CV-00411-WYD-BNB, 2010 WL 1258010, at *7 (D. Colo. Mar. 26, 2010).
9. von Tigerstrom, *supra* note 7, at 483.
10. *Id.*
11. 878 F. Supp. 2d 248 (D.D.C. 2012).
12. *Id.* at 257.
13. See Jocelyn Kaiser, *U.S. Federal Court Says Stem Cell Treatments Are Drugs*, SCIENCEINSIDER, July 26, 2012, available at <http://news.sciencemag.org/scienceinsider/2012/07/us-federal-court-says-stem-cell.html> (last visited Aug. 21, 2012).
14. Mary Ann Chirba & Stephanie M. Garfield, *FDA Oversight of Autologous Stem Cell Therapies: Legitimate Regulation of Drugs and Devices or Groundless Interference with the Practice of Medicine?*, 7 J. HEALTH & BIOMED. L. 233, 272 (2011). There is a good deal of space between the dichotomous terms in the title of their article.
15. The physicians have ceased doing so until the lawsuit is finally decided. However, von Tigerstrom, *supra* note 7, at 481–82, reports that the company “has licensed the technology to clinics offering it in China and Argentina, and is opening a stem cell culture lab in the Cayman Islands.” Stem cell tourism, anyone?
16. *See id.* at 480.
17. *Id.* at 506. For a brief commentary on the case, see Tamra Lysaght & Alastair V. Campbell, *Regulating Autologous Adult Stem Cells: The FDA Steps Up*, 9 CELL STEM CELL 393 (2011).
18. In this context, an allogeneic stem cell product is created from the genetic constitution of a different individual from the same species, whereas an autologous stem cell product is created from the same individual who will be using the product.
19. Paul S. Knoepfler, *Key Anticipated Regulatory Issues for Clinical Use of Human Induced Pluripotent Stem Cells*, 7 REGENERATIVE MED. 713 (2012).
20. Alex Philippidis, *Stem Cell Tourism Hardly a Vacation*, GENETIC ENGINEERING & BIOTECH. NEWS, (Aug. 16, 2012), <http://www.genengnews.com/insight-and-intelligenceand153/stem-cell-tourism-hardly-a-vacation/77899669>.
21. My account of the ethics of risk imposition lends itself to no quick summary. See Munzer, *Risk and Reward*, *supra* note 2, at 143-45. My basic approach is roughly Scanlonian—that is, ethical principles of risk imposition must be justifiable to each reasonable individual put at risk by, in this case, a stem cell product. See, e.g., THOMAS M. SCANLON, WHAT WE OWE TO EACH OTHER (1998); James Lenman, *Contractualism and Risk Imposition*, 7 POLITICS, PHILOSOPHY & ECON. 99 (2008).

22. See, e.g., Zubin Master & David B. Resnik, *Opinion: Reforming Stem Cell Tourism*, THE SCIENTIST, Sept. 14, 2011, <http://the-scientist.com/2011/09/14/opinion-reforming-stem-cell-tourism> (offering suggestions for thwarting the use of unproved and possibly harmful stem cell therapies). Compare the discussion of Regenexx-C, *supra* at text accompanying notes 5–20.
23. E.g., Allen Rostron, *Beyond Market Share Liability: A Theory of Proportional Share Liability for Nonfungible Products*, 52 UCLA L. REV. 151 (2004).
24. Tomas J. Philipson & Eric Sun, *Is the Food and Drug Administration Safe and Effective?*, 22 J. ECON. PERSPECTIVES 85, 90–91 (2008).
25. See generally Munzer, *Risk and Reward*, *supra* note 2, at 135–45.
26. See generally 1 DEREK PARFIT, ON WHAT MATTERS 31–174 (2011); JOSEPH RAZ, BETWEEN AUTHORITY AND INTERPRETATION: ON THE THEORY OF LAW AND PRACTICAL REASON 6–8, 143–47, 186–87, 205–08, 214–19, 367–69 (2009); JOSEPH RAZ, PRACTICAL REASONS AND NORMS 35–48 (3d ed. 1999); Robert Nozick, *Moral Complications and Moral Structures*, 13 NAT. L. FORUM 1 (1968).
27. See generally ELEANOR H. PORTER, POLLYANNA (1913).