11 Independent Agencies

11.1 Why an Independent Agency?

Any proposal to create a new regulatory institution for biomedical technologies must ensure that regulators remain independent. Only a proposal for a genuinely independent agency stands a chance to be supported by organized interest groups and by a majority in Congress. What exactly "independence" means will be discussed in some detail below, but the basic gist of the argument can easily be summarized: we consider an agency independent if none of the affected interest groups believes that other interest groups exercise undue influence over the agency decision-making. Agency independence as understood in this report is related to but distinct from the concept of independent agency familiar to legal scholars and public administrators. As we will show in more detail below, independent agencies as they exist throughout the federal government are not adequately protected against regulatory capture and political manipulations by Congress or the office of the president. They are, however, an important means to ensure genuine independence.

A quick look at the current political landscape demonstrates the crucial importance of agency independence. It is no exaggeration to say that in recent times, the scientific community has been terrified by the prospect that research freedom could be encroached upon by ideologues, religious zealots, and radical environmental groups advancing a deeply skeptical view of modern science. On the opposite side, an alliance of religious and conservative organizations is deeply concerned about unbridled reproductive medicine and what they see as growing scientific arrogance. In this political climate, the science camp has come to view any attempt to provide legal guidance in this area as the first step toward bigotry and intolerance. Conservative and religious groups, for their part, resist a regulatory approach on the grounds that it would provide a governmental stamp of approval to murderous procedures. Against this background, a proposal that does not include appropriate measures to prevent undue political interference would simply be ignored.

Supporters of unconstrained scientific research may find the concept of agency independence very attractive; in the current political environment, an independent agency would provide an effective protection against attempts by conservative and religious groups to unduly interfere with science and medicine. Protecting science is, however, not what agency independence is designed to achieve. The concept of an independent agency is neutral. One could just as well imagine a future administration very supportive of biomedical research being unable to significantly affect an independent agency constrained by a statute deemed too restrictive. In this scenario, it is the scientific community that threatens to unduly influence the regulatory independence. The concept of independence, if it means anything, denotes an

agency's ability to implement Congressional intent in accordance with broad public sentiments, possibly against the wishes of organized interest groups of any kind.

The relevance of agency independence is not limited to the U.S. context. As shown in chapter 6, countries such as Britain, Canada, and Australia have, to different extents and in different ways, endorsed this general principle. The British experience certainly suggests that agency independence as envisaged by the British Parliament is a feasible and effective proposition. In the course of its relatively short history, the Human Fertilisation and Embryology Authority has faced numerous challenges and the wisdom of its rules and policies has often been contested, yet until very recently, its legitimacy as the premiere regulatory authority in matters pertaining to reproductive medicine has not been challenged.[1] The much more recently created Australian Embryo Research Licensing Committee has received its fair share of criticisms, but to our knowledge its existence is not in danger.

Independent agencies are nothing new in our own administrative system. Since the establishment of the first independent agency in 1887, the Interstate Commerce Commission, Congress has created numerous independent agencies, including the Securities and Exchange Commission and the National Labor Relations Board (both established during the New Deal), and more recently the Consumer Product Safety Commission, the Nuclear Regulatory Commission, the Commodity Futures Trading Commission, and the Federal Communications Commission. This list is by no means exhaustive. The May 2005 Unified Agenda lists 17 independent agencies, but many more are likely to exist.[2]

But what is an independent agency in the U.S. system of government? Surprisingly, no universal legal definition of this term is available. Independent agencies can differ from each other in significant ways. Legal scholars have identified several attributes shared by most independent agencies.[3] Appointing the head of an independent agency is a presidential prerogative. Appointments require confirmation by the Senate – the president appoints with the "advice and consent" of the Senate. Unlike other heads of agency, however, the head of an independent agency does not serve "at the pleasure of the President" – the president can only remove him or her for "cause." In the case of the Federal Trade Commission (FTC), for example, the removal clause maintains that "any commissioner may be removed by the President for

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[1] This may be about to change however, as in early 2005, the House of Commons Science and Technology Committee has initiated a broad review of the HFEA's mandate. See Susan Bartlett Foote, "Independent Agencies under Attack: A Skeptical View of the Importance of the Debate," *Duke Law Journal* 1988 (1988); Science and Technology Committee House of Commons, "Inquiry into Human Reproductive Technologies and the Law: Eighth Special Report of Session 2004-05," (London: The Stationary Office, 2005); James C. Miller, "A Reflection on the Independence of Independent Agencies," *Duke Law Journal* 1988 (1988); Alan B. Morrison, "How Independent Are Independent Regulatory Agencies?," *Duke Law Journal* 1988 (1988); Aulana L. Peters, "Independent Agencies: Government's Scourge or Salvation?," *Duke Law Journal* 1988 (1988); Glen O. Robinson, "Independent Agencies: Form and Substance in Executive Prerogative," *Duke Law Journal* 288 (1988).

[2] See http://www.gpoaccess.gov/ua/browse0505.html.

[3] For an in-depth discussion of independent agencies and their position in the U.S. system of government, see Paul R. Verkuil, "The Purposes and Limits of Independent Agencies," *Duke Law Journal* 1988 (1988).

inefficiency, neglect of duty, or malfeasance in office."[4] Thus, in the U.S. system of government, agency independence has a very narrow meaning: An agency enjoys a measure of independence from the executive branch, and from the executive branch only. Congressional oversight, in its various forms, is fully preserved.

Most independent agencies are constituted as commissions of various sizes, though in principle at least, an independent agency could be governed by a single individual. To our knowledge, currently no such agency exists. Most commissions, including the Federal Trade Commission, the Nuclear Regulatory Commission, and the Securities and Exchange Commission, have a five-member board; a few operate with only three commissioners, and one, the Federal Reserve Board, is governed by seven board members.

Another typical attribute of independent agencies is stacked appointments for a fixed term of office. Stacked appointments ensure that new commissioners are replaced at a slow pace, and that the turnover remains low. The terms of office are often set so as not to coincide with the presidential term. FTC commissioners, for example, serve for a five-year term. Members of the Federal Reserve Board serve for an exceptionally long 14-year term. Other commissions operate on a three-year basis. By limiting the appointment to only one term, commissioners have greater room for maneuver; their reappointment obviously is not a consideration in their daily work. Independent commissions are constituted as bipartisan administrative units. Neither party can be represented by a clear majority – another indication of the Congressional will to insulate independent agencies from excessive political influence.

Independent commissions tend to operate in a consensual way. Commissioners debate the pros and cons of alternative courses of action, listen to expert testimony, and try to make decisions by consensus rather than by majority vote. Decision by consensus is normally the preferred option; decision by majority vote is regarded both as a recognition of the difficulty of achieving a consensus within a reasonable period of time, and of the need to avoid administrative paralysis.

A final, perhaps less common but important attribute of independent agencies is their accumulation of authority in legislative, adjudicative, and prosecutorial matters. In plain text, some independent agencies make rules, preside over legal disputes pertaining to the commission's regulatory scope, and in some cases also prosecute civil violations of the statutes they administer. Not all independent agencies perform all three tasks, and some executive agencies have been assigned at least two of these functions, so this is by no means an exclusive characteristic of independent agencies, but it seems more common for independent agencies than for executive agencies to accumulate powers. This is also the reason why some legal scholars believe that this administrative construction violates the separation of powers doctrine and is therefore unconstitutional.

But what is the rationale for Congress to create an independent agency? Traditionally, Congress has established independent agencies to oversee specific industries or policy-making

[4] See 15 U.S.C. § 41 (1982).

areas that were thought to require extensive technical expertise. Moreover, in Congress' view, the exercise of technical judgment should not be hampered or distorted by political considerations. Agency independence in this case is synonymous with technocratic decision-making: Technical experts are in the best position to select the most appropriate course of action; they do so by relying on science-based, objective criteria. Non-technical considerations are regarded as an unacceptable distortion of the decision-making process. Examples include the regulation of nuclear power plants (by the Nuclear Regulatory Commission), of financial markets (by the Securities and Exchange Commission), or of product safety (by the Product Safety Commission).

On closer examination, this rationale is anything but convincing. If technical expertise and technocratic decision-making were of such paramount importance, then it is difficult to see why the Food and Drug Administration is not an independent agency. On the other end, some would argue that the extreme independence enjoyed by the Federal Reserve Board cannot be justified on technical grounds alone. These observations suggest that the Congressional rationale for establishing independent agencies is of dubious credibility. Whatever the officially stated reasons for Congress to establish a new independent agency, its creation usually signals a Congressional desire to increase control over the agency at the expense of the president's ability to shape agency policy. Agency independence, in this sense, is simply a (perhaps marginal) shift in the relative ability of the executive and legislative branches of government to control a regulatory body. It most definitively does not represent a significant net increase in the agency's ability to implement a policy agenda that conflicts with presidential wishes or Congressional preferences. Furthermore, independent agencies, just like any other executive agency, are exposed to the lobbying efforts of innumerable interest groups. So it is not at all clear that the creation of an independent agency, notwithstanding many desirable attributes of this organizational form, would help create an agency that could operate in a genuinely independent manner.

Some commentators have argued that independent agencies are more and not less exposed to the dangers of factionalism and capture than agencies placed under the control of the president.[5] Reducing the president's powers to shape agency policy could deprive the agency of a powerful political advocate. Independence originally derived from an antiquated notion of the administrative state. In this view, an agency implementation and interpretation of the law can and should be guided exclusively by technical rationality. Accordingly, an agency should be insulated from any external interventions that might distort this allegedly impartial process of decision-making. The agency is supposed to pursue the public interest, and the means for accomplishing this goal is technical rationality. This view of the administrative state was very in vogue during the New Deal, but it lost much of its appeal soon after the end of World War II. During those days, agency independence was often synonymous with regulatory capture and factionalism. Independent agencies were more exposed to the dangers of factionalism and

[5] James F. Blumstein, "Regulatory Review by the Executive Office of the President: An Overview and Policy Analysis of Current Issues," *Duke Law Journal* 51 (2001); Easterbrook, "Presidential Review."; Lawrence Lessig and Cass Sunstein, "The President and the Administration," *Columbia Law Review* 94 (1994).

capture than executive agencies placed under the control of the president. It is in no small measure because of "arbitrary and capricious" decisions by both independent and executive agencies that the Congress in 1946 passed the Administrative Procedure Act.

In what sense, then, is an independent agency a concept worth pursuing? First, for symbolic reasons. In the eyes of the general public, it simply would not be credible on the one end to call for strong regulatory independence and on the other to reject the creation of an independent agency. Proponents of an executive agency would find themselves in the uncomfortable position of having to explain why an executive agency is actually more independent than an independent agency. Establishing an independent agency is thus a first, necessary step to ensure genuine independence.

Political symbolism is certainly not the only reason for favoring the creation of an independent agency. This organizational form is a far better match for what may be described as the two main tasks facing a regulatory agency responsible for overseeing reproductive medicine and biomedical research – implementing the Congressional mandate and adjudicating societal disputes – than an executive agency. Consider first how the agency would go about translating Congressional expectations into actual regulations. Let's assume for a moment that Congress has included a set of ethical principles in the enabling statute as outlined in chapter 3. Ethical principles, by definition, provide merely a general sense of direction. In all but the most trivial cases, they are not capable of unambiguously resolving a specific ethical dilemma, in the sense that with regard to a given medical technology or research protocol, there may be several regulatory interpretations of the same ethical principle. For example, the principle that the agency should favor therapeutic over enhancing technologies, applied to pre-implantation genetic diagnosis, could produce startlingly different regulations depending on exactly how the concept of therapy is defined, and on whether the prospective parents alone should benefit from the treatment or the benefits should be extended to the blastocysts and the future child. If Congress does not ban reproductive cloning, the agency would also have to determine whether this procedure should be considered therapeutic or enhancing. Sex-selection technologies would raise analogous interpretative problems. In all these cases, the agency would be called upon to perform a task typical of a judicial body.[6]

The agency would also be called upon to adjudicate disputes over new reproductive treatments or controversial research protocols. For example, at some point regulators may be forced to offer a legal opinion on whether the creation of so-called designer babies is compatible with the protection of the well-being of future children, or whether this procedure should be considered therapeutic in the first place. Some research protocols involving mixing human and animal reproductive tissues are also likely to require adjudication by the agency.

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[6] Some could argue that performing judicial tasks reflects Congress' failure to promulgate sufficiently specific legislation. In this view, Congress should prevent this abuse of administrative power by passing more narrowly crafted legislation. As discussed in chapter 9, this view simply flies in the face of current administrative realities. In addition, requiring Congress to take on regulatory tasks would produce a rigid statutory framework incapable of responding in a timely fashion to new medical and scientific developments.

Small decision-making bodies such as independent agencies are particularly well-suited to take on both interpretative and adjudicative tasks. Performing these tasks requires balanced judgment, a systematic examination of all relevant arguments, and an overall commitment to finding consensual solutions in a deliberative fashion. In other words, this independent agency would operate more like a court than a traditional executive agency. Its core task would consist – after listening to the views and positions of all affected parties and the general public – of deciding factual questions in a deliberative manner by applying the ethical principles set forth in the enabling legislation. Central to this decision-making body are not efficiency and effectiveness, as in the case of an executive agency responsible for implementing a Congressional mandate, but moral authority and procedural fairness, as expressed in the rationale offered to justify a certain finding of fact. This is not to say that this agency would not have to perform traditional executive tasks. We will discuss some of these tasks in chapter 13. Our claim here is simply that this independent agency's core task is mainly judicial. For this particular task, a small deliberative body would be the organizational form of choice.

The judicial nature of this regulatory body provides a *prima facie* argument against presidential powers of removal. It would be quite disturbing, inappropriate, and detrimental to our modern notions of democracy if a president felt compelled to intervene on behalf of specific political constituencies in an ongoing adjudicative procedure by removing commissioners deemed hostile. No quasi-judicial regulatory body would be viewed as an authoritative and independent arbiter if the president had the authority to remove a commissioner deemed hostile to the interest of one or the other presidential constituencies. Agency independence, in this case, is indeed crucially dependent on the president not having powers of removal.

The view that adjudicatory functions within the executive branch should be removed from presidential oversight is certainly not new. As some commentators have pointed out, the Founding Fathers placed considerable value on a unitary executive, but they also made clear that other values could on occasion trump unitariness.[7] Arguably, the independence of adjudicative functions was such a value. This is not all that surprising and quite consistent with contemporary notions of the separation of powers. This is not to say that presidents would be deprived of broad policy-making authority, or that they would loose the ability to ensure that the administrative apparatus conforms to their political priorities. The president can do so effectively through the appointment process, but also through the Office of Management and Budget (OMB) regulatory review and through presidential directives. For example, Section 1 of President Clinton's Executive Order 12866 of September 30, 1993, requires that all federal agencies, in deciding whether to regulate, take all costs and benefits into account.[8] Obviously, Executive Order 12866

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[7] Lessig and Sunstein, "The President and the Administration."; Cass Sunstein, "The Myth of the Unitary Executive," *American University Administrative Law Journal* 7 (1993).

[8] Executive Order 12866, 1993, "Statement of Regulatory Philosophy and Principles" states that (a) The Regulatory Philosophy. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of

does little to directly affect the outcome of rule-making. It does, however, provide a specific policy framework within which any agency of the federal government, independent or executive, involved in regulatory activities must operate.[9] Executive Order 12866 advances a view of the regulatory state strongly informed by cost-benefit considerations. It goes almost without saying that at least some of the ethical principles outlined in chapter 3 would produce rules that might not pass a cost-benefit test. Whether these rules would be incompatible with Executive Order 12866 is an interesting question that we are not prepared to discuss here.

Skeptics could argue that adjudicative functions should not lie with an independent agency, but rather be delegated to the judiciary. We believe that there are good reasons for keeping these functions within the executive branch. An independent commission, unlike a panel of judges, specializes in a specific and narrow aspect of the law, in this case a statute pertaining to reproductive medicine and biomedical research. Over time, this regulatory institution would develop considerable expertise in adjudicating difficult bioethical controversies; the quality of its rulings, measured by their perceived fairness in the eyes of all affected parties and the general public, would increase, and so would the agency's efficiency is delivering a ruling.

The emphasis we have placed on agency independence could suggest inattention on our part to questions of accountability. A judicial body should be shielded from political manipulations. On the other end, there is a very real danger that a quasi-judicial body, as outlined in this report, could quickly turn into an unaccountable bureaucracy with a tendency to produce "arbitrary and capricious" opinions. Inadequate accountability would be just as corrosive as factionalism and capture, and must be avoided. Our discussion could have suggested that there may be an unavoidable trade-off between agency independence and accountability. This impression is misleading. We believe that it is quite possible to ensure both agency independence *and* accountability.

The president and Congress have various means at their disposal for ensuring accountability. Congress can threaten to use the power of the purse to induce the agency to change its course, a threat used quite effectively in the past. Presidents, for their part, through their power to facilitate or impede future career moves, can exercise considerable influence on commissioners taking positions incompatible with broad public sentiments. Judicial review is also a powerful check on agency drift. These are all familiar checks and balances. With the exception of judicial review, these oversight measures could themselves be regarded as "arbitrary and capricious." For this reason, we propose to ensure accountability by other means – i.e., through mechanisms of public consultation. How a public consultation could be embedded in traditional rule-making and what its impact would be on the legislative and executive branch is the topic of chapter 12. Here, we would simply like to point out that mechanisms of public consultation are likely to obviate a long-standing problem, namely that with the ability of either branch of government to maintain

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the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. […]"

[9] Note that this directive replaced a similar one originally signed by President Reagan, and that the current president has left Executive Order 12866 in place.

accountability also comes the very real risk of excessive or inappropriate interventions by the office of the president or Congress. In sum, while advocates of a unitary executive may find it disturbing that in our proposal the president would be deprived of his or her removal powers, we believe that these powers are not necessary to protect the agency against capture, and that they could actually threaten the credibility and authority of this quasi-judicial regulatory body.

11.2 Design Considerations

Having justified in some detail why an independent commission is preferable to an executive agency with a single head, in this section we proceed to discuss several additional benefits and a few possible drawbacks of the proposed organizational format, and to examine specific implementation options.

A deliberative body of government is much better suited to resolving complex ethical dilemmas than a single head of agency. Deliberation is likely to produce better reasoned and therefore more legitimate rulings. A fair judgment also requires taking into account all perspectives, and doing so in a balanced manner. A single head of agency is simply in no position to meet all these requirements. Another reason for preferring the commission format to a single head of agency is that the decision-making process would be more transparent. Opening the commission meetings to the public would likely increase the quality of the arguments in favor of and against any given policy. It would also shield the commissioners against the most blatant attempts to manipulate the decision-making process.[10] This is not to say that private conversations in this regulatory context have no useful role to play. To the contrary, a measure of privacy is indispensable for commissioners to establish relationships of mutual trust. How exactly conflicting demands for privacy and for public access should be reconciled is not a question with a straightforward answer.

A commission, by its very nature, is less exposed to manipulative attempts by Congressional representatives. The history of the administrative state clearly demonstrates that often it is precisely Congressional representatives who advance the most parochial agendas on behalf of their constituencies. A commission format dilutes administrative authority and makes it more difficult for politicians to directly influence regulatory process. Finally, a deliberative approach to resolving ethical dilemmas is particularly well-suited to reconciling different interests and ethical positions. It also helps in crafting broadly acceptable political compromises. As shown in chapter 10, a deliberative approach to ethical controversies does not guarantee consensus or unanimity, and under certain circumstances deliberation may even sharpen the divisions among commissioners. On the other end, it is difficult to imagine addressing any ethical dilemmas in a non-deliberative fashion.

Having mentioned the benefits associated with a commission format, we should mention some potentially significant disadvantages. Scholars of public administration have pointed out

[10] Making the transcripts of public meetings available to the public, as is now common across the federal government, would also have a positive educational impact on the general public.

that independent commissions tend to attract second-rate candidates for office. An appointment to a federal regulatory commission generally is not a sufficient enticement to attract top administrative talent. This is especially the case when an independent commission's work has become somewhat of a routine. Independent agencies are also likely to be inefficient.[11] Some commentators have pointed out that a deliberative approach to rule-making and the search for consensus solutions make for slow decision-making.

These criticisms are accurate, but only in a narrow sense. The kinds of skills embodied in ambitious, top-notch administrators would be of little use in the context of a deliberative body. Making the most efficient use of bureaucratic resources to achieve a policy goal is not what the resolution of complex ethical dilemmas requires. Not only would top administrators not be attracted by this body, their appointment is unnecessary and would be counterproductive. Strong personalities with an extensive business background are a poor choice for a quasi-judicial, egalitarian, and deliberative body of government.

The quality and competence of prospective commissioners is not likely to degrade over time for the simple reason that medical and scientific progress will keep the agency's work from becoming routine. As the case of the British Human Fertilisation and Embryology Authority demonstrates, in its 14 years history, that agency rarely has formulated a policy that did not generate considerable public controversy. And while it is certainly true that in certain regulatory contexts – as in the case of product safety, for example – the commission format most likely has been the primary reason for an unacceptably slow pace of decision-making,[12] one may wonder whether in the case of nuclear power safety slow decision-making is such a bad thing. Efficiency is only one of several competing goals in designing a system of governance. A head of agency most likely would resolve ethical dilemmas in a more expeditious way, but protracted judicial review would more than compensate for increased efficiency at the regulatory stage. One simply has to accept the fact that deliberative bodies are not designed to operate in an efficient manner, and that producing fair and just rules in this case takes precedence over bureaucratic efficiency.

What criteria, then, should inform the design of this commission? At the international level, there seems to be a growing consensus that a regulatory body in the area of reproductive medicine and biomedical research should be composed of representatives of specific constituencies. The British have been the first to adopt this approach. As discussed in chapter 6, the HFEA governing body consists of 18 persons. In addition to representatives of the fertility industry and the medical community, this body includes a majority of what may be called laypersons, i.e., individuals who do not represent a clearly identifiable interest group. This was

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[11] Commentators seem to agree that independent agencies are an inefficient form of government, yet there is precious little evidence of actual inefficiency, if by evidence we mean a systematic, comparative analysis of decision-making within different types of government organizations. It is true that during the New Deal, the Golden Age of independent agencies, regulatory capture and organizational dysfunction were of almost Biblical proportions, as documented, for example, in James M. Landis, *The Administrative Process* (New Haven: Yale University Press, 1938). modern independent agencies do not bear much resemblance to their ancestors.

[12] Elliot Klayman, "Standard Setting under the Consumer Product Safety Amendments of 1981 – a Shift in Regulatory Philosophy," *George Washington Law Review* 51 (1982).

and remains the British solution to the problem of capture by factional interests. Perhaps inspired by the British precedent, the Australian and Canadian governments have also established regulatory bodies structured in functional terms, though in these latter two cases, it appears that preventing regulatory capture was not of paramount importance in allocating the available slots.

We believe that an independent agency for regulating reproductive medicine and research in the United States should not be thought of and designed as a representative body of key political interests. Attempts to ensure representation would likely produce a large regulatory body consisting of many narrow and mutually exclusive interests. Affected constituencies are ill-defined societal groupings with a tendency to proliferate. For example, it may not be sufficient to ensure that the interests of prospective parents are adequately represented, because at some point, lesbians and homosexual associations may feel that their constituents' interests are sufficiently distinct from those of traditional couples as to deserve separate representation. This distinction, in turn, may encourage singles to claim their own separate seat at the regulatory table. The ART industry and the scientific communities are likely to suffer from the same fragmentation tendencies. As a general rule, the more homogeneous a political constituency becomes, the more specific and narrow its interests, and the more difficult it is for its representatives to accept political compromises, let alone produce consensual solutions. This is not to say that factional interests should be ignored, but merely that these groups should have an opportunity to be heard in a different setting.[13]

Independent commissions are generally quite small. With very few exceptions, U.S. independent agencies consist of only three to five commissioners (the Federal Reserve Board being a noteworthy exception). Bureaucratic efficiency would require keeping the number of commissioners small, but in this case, efficiency is neither the only nor the most important design consideration, nor is size as detrimental to efficiency as commentators tend to believe. The British and Australian regulatory bodies in the area of biomedicine are considerably larger. The HFEA is governed by an 18-member body, as stated above, while the Australian Embryo Research Licensing Committee consists of nine members. Whether the size of the HFEA governing committee has had a negative impact on the ability of the British regulators to oversee reproductive medicine in an efficient way is an interesting but also very difficult question to answer. Anecdotal evidence suggests that in controversial and highly visible cases, the HFEA indeed proceeded at a glacial pace. If one examines the HFEA decision-making record over its entire existence, however, it is difficult to depict this agency as a paragon of bureaucratic inefficiency. So while to U.S. commentators an 18-member independent commission may seem exceedingly large, experience demonstrates that a regulatory body of this size is quite capable of meeting its public mandate.

Another reason for not attaching too much importance to the size of a regulatory body is that, in the case of the HFEA, for example, the slow pace of decision-making was not as much a

[13] Establishing specific commission positions may also be interpreted as an unconstitutional limitation on the presidential prerogative to appoint executive officers.

reflection of the committee size as a conscious choice by the HFEA to resolve deep divisions among its members by consensus rather than by majority vote. Conclusive evidence is not available, given the British penchant to conduct business in a rather informal manner, but anecdotal evidence suggests that the HFEA often has strived to find consensual answers to the ethical dilemmas. Taking a vote would of course make the decision-making process considerably more efficient, but efficiency would have been achieved at the cost of legitimacy.

One important reason for not envisaging a large commission is that a smaller commission has a better chance to produce a genuine consensus. Yet small size has its own problems. Small bodies are exposed to the risks of individual idiosyncrasies and perverse group dynamics in a way that larger bodies are not. Some commissioners may become too influential; others may become irrelevant. By contrast, the larger the group, the less idiosyncratic it is likely to become. The influence of individual members becomes smaller the larger the body is. In addition, members of a very small regulatory body may quickly become trapped in mechanical reactions and argumentative frameworks that would make it very difficult for this board ever to achieve consensus. For this reason alone, the periodic renewal of commission members may be crucial to maintaining the commission's ability to regulate.[14] Absent empirically validated rules for determining the optimal size of a small regulatory body such as the one envisaged in this chapter, we believe that a commission of seven to nine members represents a reasonable compromise between the pros and cons of large versus small decision-making bodies.

Consensual solutions to complex ethical dilemmas contribute to increasing the legitimacy of a controversial regulatory body in a way that a majority vote does not, though it is not entirely obvious why this is so. Perhaps a consensual response to difficult ethical dilemmas reinforces the regulators' moral authority in the eyes of the general public. To the extent that all affected parties and the public regard this regulatory body as genuinely independent, consensual solutions would certainly make controversial policies more acceptable to the loosing factions. For this reason, organizational design should privilege structures and procedures that favor consensus solutions.

Very little consolidated knowledge is available on how to promote achieving a consensus. Deliberation, as often noted in this report, certainly is an important contributing factor, but its importance should not be overemphasized. Just as important in this context is the actual composition of the regulatory body with regard to the commissioners' views and ethical inclinations. Commissioners with weak preferences are preferable to candidates with very strong views if finding consensus is indeed of paramount importance. Against this background, appointing professional bioethicists or individuals with considerable ethical expertise may be counterproductive. The appointment of what may be described as thoughtful generalists would promote a deliberative process that starts from genuine ambivalent positions and fluid preferences rather than from clearly articulated interests. The appointment of generalists all but ensures that these individuals would not have strong allegiances to any particular constituency. Just as important is ensuring that no particular view is overrepresented. In practice, this

[14] In this regard, see Moreno, *Deciding Together. Bioethics and Moral Consensus*, ch.8.

requirement is very difficult to implement, as the agency is called upon to regulate disparate issues likely to produce different distributions of individual positions.

An obvious way to ensure consensus is for the Congress to mandate consensual decision-making in the enabling legislation. This extreme measure would ensure that the agency will promulgate only broadly supported rules and regulations, but it would also mean that as a matter of practice, this regulatory agency will produce very little legal guidance. And consensus, in many cases, may simply reflect a political compromise and not a genuine common view achieved in a deliberative manner. Consensus through compromise may be an acceptable alternative to genuine consensus when the commissioners have clear and strong preferences. In this case, deliberation will contribute to clarifying the commissioners' positions, but it is unlikely to cause the commissioners to change their ethical preferences. This outcome may not be satisfactory to advocates of deliberative democracy, but it may well be the only available option short of deciding by majority vote – an alternative that, considering its corrosive impact on the moral authority of a regulatory body, is far less attractive.[15]

In the world of politics, it is unrealistic to expect that even the best-intentioned and thoughtful commission would always produce a consensus. One possible alternative to making choices either by consensus or by majority voting is to invest the chairperson with the authority to decide on a case-by-case basis whether an ongoing rule-making process is likely to produce a consensus. Should he or she determine that a consensus could be achieved, he or she may decide to invest more time in deliberation; otherwise, he would simply call for a vote. Alternatively, the enabling legislation could provide for a fixed, maximum period of deliberation, say three months, followed by a vote. Depending on the issue under consideration, a simple majority could suffice; in more divisive cases, a supermajority may be required.

If designed according to the criteria discussed in this report, a regulatory commission is much more likely to promulgate consensus policies than the preceding discussion indicates. The commission's deliberations would take place at an advanced stage of the rule-making process. At that stage, the commissioners would be able to review the range of positions advocated by a wide range of affected and interested parties, as well as to gauge the public's response to various policy options emerging from a process of public consultation. As a practical matter, it may not always be possible to conduct public consultation, and in some cases the consultation may not produce an unambiguous outcome. But to the extent that a clear public inclination emerges, it would dramatically reduce the potential for gridlock.

In discussing possible implementation options, we have privileged legitimacy, moral authority, and consensus over efficiency, representativeness, and ethical expertise. These choices

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[15] There is no consensus on the actual value of deliberation in the regulatory and more generally in the political context. In a recently published book, Judge Richard Posner has argued that deliberation is of little value to the functioning of modern representative democracies. Cf. Posner, *Law, Pragmatism, and Democracy*. That the role of deliberation is not as straightforward as sometimes assumed is not in dispute. But it would be difficult to argue that deliberation has no impact, even on highly opinionated individuals. The change of heart displayed by some solidly conservative Supreme Court justices seems to indicate that even highly competent and opinionated individuals in a deliberative context may re-examine their views.

should not be taken to suggest that the latter design considerations are unimportant, but only that there are trade-offs in the design of an independent regulatory agency. In this sense, our approach departs significantly from that of the British. In our view, representativeness is not sufficiently important as to warrant explicit consideration in the design of our independent commission. Nor is efficiency so important as to warrant reducing this independent agency to a three-member body, though it is sufficiently important as to induce us to avoid recommending an 18-member panel. Finally, we believe that ensuring the legitimacy and credibility of this body should have priority over its ethical and scientific expertise. This is not to say that representativeness and ethical and scientific expertise should be neglected, but rather that organized interest groups should have a chance to be heard in a different setting, and that the commission should be granted access to ethical and scientific expertise by bureaucratic means.

11.2.1 The Advisory Board

Many of the limitations characterizing the British, Australian, and Canadian approaches to regulating biomedicine can be traced to organizational trade-offs. It is simply not possible to design a small deliberative body that is authoritative and legitimate and at the same time broadly representative of all affected parties and knowledgeable in ethical, medical, and scientific matters. For this reason, we propose to complement the independent commission with an advisory board. As its name suggests, the board would not have regulatory authority. In essence, its job would be to serve as an institutionalized communication platform between the commissioners, the regulated community, and the general public.

The board would be designed to ensure representativeness and technical competence in all relevant scientific fields and in bioethics. It would operate in a deliberative fashion, but would not be required to produce consensus recommendations. Majority and minority positions would not only be allowed but welcomed, for the reasons discussed in chapter 10. Finally, the board would not be subject to size constraints to the same extent as the independent commission, and could be considerably larger.

Representativeness requires elaboration. The advisory board would be representative of all affected parties, but not as this term is normally understood. An affected party should not necessarily be equated to any existing professional or trade association. Affected parties include the ART industry, the scientific community, the biotech industry, and patients. Each sector would receive a fixed and equal number of slots. Trade and professional associations and their members would be responsible for selecting and nominating suitable candidates. For example, the scientific community may decide that it wants to be represented by the American Association for the Advancement of Science. In this case, AAAS would represent not only its own members, but also the members of other scientific societies, such as the Federation of American Societies for Experimental Biology or the American Society for Microbiology. Analogous choices would have to be made by the ART industry and its various trade and professional associations.

There are good reasons for proposing such a broad concept of representativeness. As repeatedly discussed in this report, the broader the sector represented by a member of this

advisory board, the higher the chances that the advisory board will succeed in generating broadly acceptable policy recommendations. To use the terminology developed in chapter 10, the less homogenous the sector represented, the less likely it is that the advisory board will display polarization tendencies.

Some commentators have observed that advisory panels, especially those meant to provide scientific guidance, may have both a subtle and a disproportionate influence on regulatory agencies.[16] How an ethical dilemma is framed and what language and metaphors are used to describe the relevant ethical concerns are choices likely to affect how an independent commission will resolve a controversy. This is why it is important that all societal perspectives be represented on this panel, including those of laypersons. A layperson is an individual who does not represent the interests of the ART industry, patients, the scientific community, or the biotech industry. Furthermore, this person is not immediately or substantially affected by advances in reproductive medicine or biomedical research, and does not have financial interests in the sectors subject to the commission's regulatory authority.

There are at least four reasons for appointing a substantial number of laypersons to the advisory board. Laypersons are likely to advocate a notion of harm not limited to economic costs or to narrowly defined health risks. They would also prevent the advisory board from focusing exclusively on procedural matters. In addition, a significant number of laypersons would contribute to preventing or mitigating group polarization. To this end, it would not be sufficient, as is common practice on many science advisory boards, to appoint only one layperson. Depolarization can only take place if all relevant views are represented in roughly equal numbers. A fourth and final reason for including laypersons on the advisory board is their policing role. By virtue of its position between the independent commission and the affected parties, the advisory panel could accumulate considerable power and influence. As for any other broker, the role of this advisory board could be both beneficial and pernicious. On the one end, it could actively promote collaboration, consensus, and compromise. Alternatively, it could promote a political agenda of its own.[17] Absent independent board members, it is quite possible for a societal sector to obtain support for a policy in its interest in return for the promise to return the favor in the future.

How many laypersons should be appointed? Our discussion of group polarization suggests that for laypersons to develop a genuinely independent voice, their weight on the commission should be comparable to that of other societal interests. For this reason, we propose to appoint at least as many laypersons as representatives of any one of the other societal sectors. If the enabling legislation does not require the advisory board to produce consensus recommendations,

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[16] Sheila Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (Cambridge, MA: Harvard University Press, 1990).

[17] This is a somewhat unusual illustration of what may be called a "political entrepreneur." As pointed out by Ronald Burt, an entrepreneur is an individual (or an organization) that has identified two disconnected parties who could each benefit from cooperation but are unable to do so by themselves. Ronald S. Burt, *Structural Holes. The Social Structure of Competition* (Cambridge, MA: Harvard University Press, 1992).

then an equal number of representatives for all societal sectors, including the general public, would be acceptable. On the other hand, if recommendations on the advisory board are made by majority vote, then the number of appointed laypersons should be much larger – and equal that of all interested parties combined.

The advisory board would also work with the commission to implement and operate a suitable system of monitoring and compliance assurance. This move has both obvious and subtler benefits. By delegating monitoring functions to the advisory board, the commission would be able to focus on its core task. Less intuitively, delegation of monitoring and compliance assurance to third parties is likely to produce higher levels of compliance and, in the long run, to increase the legitimacy of government regulation in the eyes of the regulated community. We will return to this topic in chapter 13.[18]

To prevent this advisory from becoming unaccountable to its constituencies, the enabling legislation could require that board members be in close contact with their constituencies. The importance of this measure can hardly be overemphasized. Absent any accountability mechanism, board members would be free to advance a political agenda that may be entirely detached from the constituencies they supposedly represent. As noted in chapter 8, little is known about the attitudes of scientists, reproductive doctors, or biotech companies on a broad range of contested policy questions. There is some evidence that these constituencies do not always endorse their association's positions. Whether, for example, scientists share the views and positions of the AAAS or any one of the many scientific societies operating in Washington is debatable. Some scientific societies do make some efforts to consult with their members on important issues, but these are exceptional cases. It is quite possible that the associations' positions in the area of reproductive medicine and biomedical technologies are aligned with their members' views; yet absent specific mechanisms of consultation, this question cannot be answered.

This requirement would not be as unusual as it may seem. As a matter of practice, many trade and professional organizations already consult with their members on various issues of mutual interest. And one should remember that there are significant benefits to implementing this measure. By adopting a robust mechanism of internal consultation, the legitimacy of the positions represented on the advisory board would greatly be strengthened.

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[18] The delegation of monitoring and compliance assurance functions to private parties is a classic example of what is sometime referred to as "collaborative governance." Jody Freeman, "Collaborative Governance in the Administrative State," *UCLA Law Review* 45 (1997); Jody Freeman, "The Private Role in Public Governance," *New York University Law Review* 75 (2000); Lester M. Salamon, *Partners in Public Service: Government-Nonprofit Relations in the Modern Welfare State* (Baltimore, MD: Johns Hopkins University Press, 1995). Collaborative governance describes an approach to government in which a government agency plays a prominent role, but is by no means the only relevant actor in the implementation of public policies.

11.2.2 The Advisory Board as a Board of Directors?

The appointment of representatives of the general public to a federal advisory board is certainly unusual within government, but it would not be exceptional in the private sector. The type of advisory board envisaged in this report is not too dissimilar from a board of directors. In the United States, it is common practice to appoint independent board directors, but this corporate role is relatively new. To appreciate its importance, it is instructive to revisit the motivations for creating independent board members.

In the late 1970s, a string of highly visible corporate scandals prompted the business and legal communities to reexamine the then-dominant approach to corporate governance.[19] At the time, the debate was informed by the assumption that poor corporate governance was the direct consequence of the sharp separation of ownership and control. In a nutshell, shareholders "own" the corporation, but they have very little say in how it is managed. Conversely, management is largely responsible for both strategic decisions and the day-to-day operations, but it has few if any property rights in the firm. One of the main tasks of the board of directors, then, is to ensure that the shareholders' and senior management's interests are aligned. This includes monitoring strategic decisions and preventing opportunistic behavior by senior management – i.e., management choices designed primarily to benefit senior management to the detriment of the company.[20]

As a matter of practice, this laudable construction has been of limited effectiveness. Because senior management often appoints the board members, and because those board members used to be subordinates, their willingness to intervene in managerial decisions is limited. In other cases, top individuals in management would simply appoint themselves to the board. Not surprisingly, then, early studies found that boards of directors play a largely passive role in governing corporations and are in no position to challenge senior management's decisions.[21]

A proposal that eventually garnered considerable support in both the legal and business communities was the appointment of independent or outside board members. Independent directors were meant to increase both the independence of the board of directors from top management and the board's ability to prevent opportunistic behavior. The notion of the independent (or outside) director is itself broad, and can be interpreted in various ways. Formally, an outside director is an individual who is not currently employed by the corporation he or she is meant to oversee. Practically, this may include former employees, retired executives,

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[19] Stephen M. Bainbridge, "Independent Directors and the ALI Corporate Governance Project," *George Washington Law Review* 61 (1993); Melvin A. Eisenberg, "Corporate Governance: The Board of Directors and Internal Control," *Cardozo Law Review* 19 (1997); Roberta S. Karmel, "The Independent Corporate Board: A Means to What End?," *George Washington Law Review* 52 (1984); Mark J. Loewenstein, "The SEC and the Future of Corporate Governance," *Alabama Law Review* 45 (1994).

[20] "Opportunistic behavior" indicates the pursuit by senior management of its own financial interests to the detriment of shareholders' best interests.

[21] Myles L. Mace, *Directors: Myth and Reality* (Boston: Graduate School of Business Administration, Harvard University, 1971); Lewis D. Solomon, "Restructuring the Corporate Board of Directors: Fond Hope: Faint Promise?," *Michigan Law Review* 76, no. 4 (1978).

or individuals who have been selected by the CEO because of their close personal ties to top management. These individuals, while technically outsiders, do not meet any strong, substantive notion of independence.[22]

Other commentators have submitted that the outside director's role is not simply one of monitoring senior management on behalf of the shareholders, but of representing a broad range of societal constituencies, including employees; representatives of women, minorities, and environmental groups; key corporate customers; consumer groups; representatives of the financial community; and large institutional investors. The inclusion of these stakeholders serves several purposes, including obtaining access to information, reducing coordination costs, facilitating access to capital, obtaining independent advice, providing a mechanism of early warning, and, last but not least, protecting the corporation's public image.[23]

Over the last 20 years, the composition of U.S. boards of directors has shifted significantly to reflect these demands. As of 1998, corporate boards of publicly traded corporations had on average 11 directors, but only two inside directors, down from three inside directors in 1993 and five in 1973.[24] Paradoxically, it is not entirely clear that the inclusion of outside directors has improved corporate boards' ability to prevent corporate misconduct. The empirical evidence in this regard is mixed.[25] There are straightforward reasons for doubting the effectiveness of outside directors, some of which we have already alluded to: Outside directors may be insiders in disguise. They may lack either the expertise or the resources (or both) to closely and competently monitor senior management. Crucially, they may not have access to the information necessary to accurately assess the performance of senior management. Lastly, they may not be inclined openly to challenge senior management and risk losing their positions on the board.[26]

Perhaps paradoxically, independent board members are much more likely to meet the expectations imposed on them in the regulatory context than in the business sector. Monitoring the independent commission is a straightforward task, and concerns regarding the competence of these board members are of secondary importance, because their responsibility would not entail assessing complex technical matters. In short, the effectiveness of independent board members is likely to be far greater in government than in the private sector.

11.2.3 Appointment Rules

Identifying suitable appointment criteria for independent board members presents a bit of a challenge. There is certainly no dearth of organizations that would feel quite comfortable

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22 Victor Brudney, "The Independent Director: Heavenly City or Potemkin Village?," *Harvard Law Review* 95, no. 3 (1982).

23 Lynne L. Dallas, "The Multiple Roles of Corporate Boards of Directors," *San Diego Law Review* 40 (2003), p.796-800.

24 Ibid., p.787.

25 For a discussion see, Kathleen A. Farrell and David A. Whidbee, "The Consequences of Forced CEO Succession for Outside Directors," *Journal of Business* 73, no. 4 (2000).

26 Brudney, "The Independent Director: Heavenly City or Potemkin Village?."

suggesting candidates. They include religious organizations such as United States Conference of Catholic Bishops and the Southern Baptist Convention, socially conservative organizations such as the Family Research Council, and secular groups such as the Center for Genetics and Society. Most of them would likely see themselves as legitimate representatives of the general public, or at least as representing views not associated with the regulated community. Each of these groups would inject a distinctive perspective into the debate and could be expected to oppose the ART industry and the scientific community on many key issues. From a pluralist perspective, this indeed would seem a natural way to select independent board members.

Our analysis of the current legislative stalemate in chapter 10 suggests that this would not be a wise move. By mechanically appointing representatives of opposing interest groups, we would simply replicate on a smaller scale the current political gridlock. Furthermore, including constituencies on the advisory board that are not directly and negatively affected by regulatory interventions could be problematic, if not downright arbitrary. In the current litigious climate, it would be very difficult to justify why one particular organization should be preferred to an equally credible group. Conceivably, one could envisage adopting the same procedure laid out for appointing the representatives of affected parties: Interested organizations are responsible for identifying broadly acceptable candidates for the available slots. In this case, however, we are not dealing with a reasonably homogeneous organizational universe, and there is little chance that these organizations would agree on common candidates. For these reasons, appointing laypersons in the narrow sense of this term is a preferable option.

We propose that the head of an executive agency – for example, the head of the Department of Health and Human Services – be charged with appointing independent board members. The enabling legislation should provide considerable guidance as to what constitutes an independent commissioner. This point should not be underestimated. Even a cursory examination of an average advisory board charter would demonstrate that agency heads have a tendency to ignore the Federal Advisory Committee Act's calls for "fair and balanced" appointments, instead simply filling these slots with political allies. Several desirable characteristics of an independent advisory board member have already been identified: An independent board member should not have strong ties to the ART or the biotech industries or to the scientific community. A financial interest in the ART or biotech industries would most likely be regarded as prejudicial. A biomedical scientist would also not qualify for a position as an independent board member, though perhaps other natural scientists and in particular social scientists might. An independent board member should not have close relatives affected by medical conditions that could be cured by promoting certain types of research.[27] Most importantly, perhaps, these individuals should bring with them the analytical skills and life experience necessary to navigate complex questions at the intersection of ethics, science, and medicine.

[27] We are certainly not suggesting that the patients' interests should be ignored. We believe that their interests are adequately represented by both patient groups and the scientific community.

How should these individuals be identified? Standard random sampling techniques followed by a standardized interview would produce a sizeable pool of suitable candidates. We believe this approach is superior to the British approach in terms of procedural fairness, in that it would not be subject to self-selection bias, and the selection criteria would be established in advance. In order to further reduce possible sources of administrative drift, independent board members could be selected at random from the pool of suitable candidates. In turn, this suggests that in addition to the selection criteria discussed above, it may be necessary to ensure balance in terms of regional representation and socio-demographic characteristics. Alternatively, the head of agency could personally select independent board members based on a personal conversation. Selection through a head of agency would probably identify better-suited candidates, but in the current political climate, it is unlikely to be acceptable to all affected parties. The technocratic alternative may not produce equally capable independent directors, but it is a practicable solution and would not be regarded as biased.[28]

[28] The novel nature of this appointment process may require Congress to periodically revisit the enabling legislation and update appointment rules and procedures based on past experience.

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