## 1 – infrastructure DA

#### Reconciliation passes now – Biden PC and tight timetables makes the margin for error literally ZERO

Elliott, 9-16 (Philip Elliott is a Washington Correspondent for TIME. Before joining TIME in early 2015, he spent almost a decade at The Associated Press, where he covered politics, campaign finance, education and the White House. He is a graduate of the E.W. Scripps School of Journalism at Ohio University, September 16, 2021, accessed on 9-17-2021, Time, "Democrats Face a Grueling Two Weeks as Infighting Erupts Over Infrastructure", https://time.com/6098810/house-democrats-reconciliation/)//babcii

House Democrats yesterday finished penning a 2,600-page bill that finally outlines the specifics of their ambitious “soft” infrastructure plan that won’t attract a single Republican vote. But no one was really rushing to Schneider’s for bottles of bubbly. For a party ready to spend $3.5 trillion to fund its social policy agenda, there were plenty of glum faces on Capitol Hill.

In fact, one key piece of the legislation—a deal that would finally let Medicare negotiate lower prices with drug companies—fell apart in the Energy and Commerce Committee when three Democrats voted against it. It found resurrection a short time later when Leadership aides literally plucked it from the Energy and Commerce team and delivered it to the Ways and Means Committee for its approval instead. Even there, though, one Democrat voted against it, saying the threat it posed to pharmaceutical companies’ profits would doom it in the Senate. “Every moment we spend debating provisions that will never become law is a moment wasted and will delay much-needed assistance to the American people,” Rep. Stephanie Murphy of Florida later argued.

Put another way? Brace for some nasty politics over the next two weeks as House Speaker Nancy Pelosi tries to get this bill to a vote before the budget year ends on Sept. 30. And those 2,600 pages had better be recyclable.

Democrats can only afford three defectors if they want to usher this bill into law, and they’re perilously close to failure. So far, five centrist Democrats in the House have said they prefer a scaled-back version of the Medicare component. But if Pelosi gives the five centrists that win, she risks losing the support of progressives who are already sour that things like a punitive wealth tax and the end to tax loopholes aren’t present in the current version of the bill.

As it stands now, letting Medicare negotiate drug prices would save the government about $500 billion over the next decade. The scaled-back version doesn’t have an official cost, but a very similar version got its score in the Senate last year: roughly $100 billion in savings. Because Democrats are using a budgeting loophole to help them avoid a filibuster and pass this with bare majorities, that $400 billion gap matters a lot more than on most bills. Scaling back the Medicare savings means they would also have to scale back their overall spending on the bill—a big line in the sand for progressives who say they’ve already compromised too much.

All of this, of course, comes as President Joe Biden and his top aides in the White House have been trying to get Senate centrists onboard. Just yesterday, he met separately with Sens. Kyrsten Sinema and Joe Manchin, fellow Democrats who have expressed worries about the $3.5 trillion price tag but have been vague about what exactly they want to cut back on. With the Senate evenly divided at 50-50, and Vice President Kamala Harris in position to break the ties to Democrats’ victories, any shenanigans from those two independent thinkers scrambles the whole package.

Oh, and that other bipartisan infrastructure plan that carries $550 billion in new spending? It’s still sitting on the shelf in the House. Pelosi said she’d bring it to the floor only when the bigger—and entirely partisan—bill was ready. And there’s plenty of grumbling about that package, too.

If this is all beginning to sound like a scratched record that keeps repeating, it’s because this has become something of a pattern here in Washington. Things look pretty grim for legislation in town these days, despite Democrats controlling the House, the Senate and the White House. Their margin for error is literally zero, and so hiccups from a half-dozen centrists can forewarn a doomed agenda.

So far, Pelosi has been a master of holding the line on crucial votes and has managed to maneuver her team to victories, including on an earlier pandemic relief package that passed with only Democratic votes. Now she’s trying again, but the clock is ticking, and $3.5 trillion is an eye-popping sum of money that rivals the spending the United States unleashed to close out World War II.

#### Plan requires significant PC which Biden can’t afford to spend– Pharma, GOP, allies, and long negotiations.

Bhadrakumar ’21 [M.K., Retired Ambassador; Columnist for Hindu and Deccan Herald Indian newspapers, Rediff.com, Asia Times and Strategic Culture Foundation, Moscow Previous positions: career diplomat for 30 years in the Indian Foreign Service: served in the Indian Embassy in Moscow (1975-1977; 1987-1998); Under Secretary (1977-1979), Joint Secretary (1992-1995), Director (1989-1991), Iran-Pakistan-Afghanistan Division & Kashmir Unit, Foreign Ministry; held posts in the Indian Missions in Bonn, Colombo, Seoul; Charge d’Affaires, Indian embassies in Kuwait and Kabul; Acting/Deputy High Commissioner in Islamabad; Ambassador to Turkey and Uzbekistan., “Biden’s Decision on TRIPS Waiver is Political Theatre”, 05-08-2021, https://www.newsclick.in/biden-decision-TRIPS-waiver-political-theatre]//pranav

The US pharmaceutical industry and congressional Republicans have already gone on the offensive blasting Biden’s announcement saying it undermines incentives for American innovation. Besides, the argument goes, even with the patent waiver, vaccine manufacturing is a complex process and is not like simply flipping a switch. Sen. Richard Burr, the top Republican on the US Senate Health Committee, has denounced Biden’s decision: “Intellectual property protections are part of the reason we have these life-saving products; stripping these protections only ensures we won’t have the vaccines or treatments we need when the next pandemic occurs.” The Republican senators backed by Republican Study Committee Chairman Jim Banks propose to introduce legislation to block the move. Clearly, Biden would rather spend his political capital on getting the necessary legislation through the Congress to advance his domestic reform agenda rather than spend time and energy to take on the pharmaceutical industry to burnish his image as a good Samaritan on the world stage. Conceivably, Biden could be counting on the “text-based negotiations” at the WTO dragging on for months, if not years, without reaching anywhere. The US support for the waiver could even be a tactic to convince pharmaceutical firms to back less drastic steps, like sharing technology and expanding joint ventures, to quickly boost global production. So far, COVID-19 vaccines have been distributed primarily to the wealthy countries that developed them, while the pandemic sweeps through poorer ones, such as India, and the real goal is, after all, expanded vaccine distribution. Biden is well aware that there will be huge opposition to the TRIPS waiver from the US’ European allies as well. The British press has reported that the UK has been in closed-door talks at the WTO in recent months along with the likes of Australia, Canada, Japan, Norway, Singapore, the European Union and the US, who all opposed the idea.

#### PC key to pass reconciliation – and it’s fragile now.

Kapur 8/22 (Sahil, national political reporter for NBC News, “Honeymoon over? Afghanistan chaos comes at a critical moment for Biden's agenda,” 8-22-2021, NBC, URL: <https://www.nbcnews.com/politics/white-house/honeymoon-over-afghanistan-chaos-comes-critical-moment-biden-s-agenda-n1277338>, //RN)

WASHINGTON — President Joe Biden’s honeymoon with congressional Democrats appeared to reach an abrupt halt last week when a number of his allies on Capitol Hill began pummeling his execution of the U.S. withdrawal from Afghanistan, promising investigations. It’s a precarious moment for Biden, who needs to save his political capital to pass his ambitious agenda with thin Democratic majorities. House leaders are battling dissent among moderate lawmakers skeptical of the dual-track strategy to approve a $550 billion infrastructure bill and a $3.5 trillion package to expand the social safety net and raise taxes on the wealthy. Some insiders see a new phase for relations between Biden and Democrats. “The relationship has certainly hit a rough spot,” said Jim Manley, who was an aide to former Senate Democratic leader Harry Reid of Nevada. “On a whole host of issues, he’s had a pretty good run since becoming president. Now I think the relationship is going to get a little trickier from here on out.” He said he was “surprised by the tough tone” that key Democratic committee chairs like Rep. Gregory Meeks of New York and Sen. Bob Menendez of New Jersey took on Afghanistan, adding that they appear determined to conduct “rigorous” oversight of Biden, their fellow Democrat. The larger political impact of the chaos in Afghanistan is unclear. Polls taken during the chaos found that Americans still prefer withdrawing over remaining. But the situation has enveloped the White House in a near-term crisis that may limit its persuasive powers over Democratic lawmakers. An NBC News poll released Sunday found that Biden's job approval rating is 49 percent, while 48 percent of U.S. adults disapprove. That is down from April, when Biden drew 53 percent approval and 39 percent disapproval. From Afghanistan to Covid, Biden faces most turbulent week in office AUG. 20, 202107:02 Dan Pfeiffer, who was a senior adviser to former President Barack Obama, said he doesn’t believe the situation will harm Biden’s agenda, but he said the concern is understandable. “Democrats have so little margin of error in Congress that even a little bit of turbulence is concerning, and the instinct for self-sabotage in centrist Democrats is always prevalent,” he said. Pfeiffer said Biden’s popularity will have an impact on Democrats down the ballot in the congressional elections next year, giving them an incentive to strengthen him and his presidency. “From the perspective of raw politics, the urgency to quickly pass the Biden legislative agenda is increased by recent events. Congressional Democrats need a strong Biden to have any chance of holding the majorities,” he said. “If the president takes a political hit from what's happening in Afghanistan, passing very popular, impactful legislation is the best way to ensure that blip is temporary.” The Senate has passed a $550 billion infrastructure bill on a vote of 69-30. The House is set to return Monday and kick off the process of advancing the bill and the separate $3.5 trillion budget resolution. Speaker Nancy Pelosi, D-Calif., has said the infrastructure legislation won’t get a vote until the Senate passes the multitrillion-dollar bill, which has sparked dissent from moderates. And those moderates are more likely to stick with Biden if their voters support him. “I am curious to figure out how much this is actually going to hurt President Biden. It’s probably a moving target for members,” Kristen Hawn, a former Democratic aide for the moderate Blue Dog Coalition, said of the Afghanistan conundrum. “I don’t think we’ll know that immediately. This is still playing out. “I do think that Democratic allies of the president want to deliver a win for him,” she said. “The bipartisan bill would be a very big win for the president at a very troubling time right now. There would be an incentive there to pass something, have it signed into law. Particularly with infrastructure, there are real-world impacts. People can see it.” A group of centrists, including Rep. Josh Gottheimer, D-N.J., is pushing for a swift vote on the infrastructure bill before the House proceeds to the budget bill. But Pelosi has said infrastructure doesn’t have the votes to pass unless it is linked to the larger package, which is a top priority for progressive lawmakers. Pelosi needs all the help she can get from Biden to get most reluctant Democrats to back her plan. “It’ll be interesting to see if Democrats, especially in the House, think he is weakened and they try to jam him on infrastructure and reconciliation,” Manley said. “Presidents and their staff as a general rule like to preserve their political capital for tough times. And they’ve done a good job of doing that so far,” he said. “But based on how difficult this is, they’re going to have to start calling in some chits.”

#### Infra’s k2 stopping existential climate change – warming is incremental and every change in temperature is vital

Higgins 8/16 [Trevor, Senior Director, Domestic Climate and Energy, “Budget Reconciliation Is the Key to Stopping Climate Change”, 08-16-2021, https://www.americanprogress.org/issues/green/news/2021/08/16/502681/budget-reconciliation-key-stopping-climate-change/]//pranav

The United States is suffering acutely from the chaotic changes in climate that scientists now directly attribute to the burning of fossil fuels and other human activity. The drought, fires, extreme heat, and floods that have already killed hundreds this summer across the continent and around the world are a tragedy—and a warning of worsening instability yet to come. However, this week, the Senate initiated an extraordinary legislative response that would set the world on a different path. Enacting the full scope of President Joe Biden’s Build Back Better agenda would put the American economy to work leading a global transition to clean energy and stabilizing the climate. A look at what’s coming next through the budget reconciliation process reveals a ray of hope that is easy to miss amid the fitful negotiations of recent months: At long last, Congress is on the verge of major legislation that would build a more equitable, just, and inclusive clean energy economy. This is our shot to stop climate change. Building a clean energy future must start now Until the global economy stops polluting the air and instead starts to draw down the emissions of years past, the world will continue to heat up, blundering past perilous tipping points that threaten irreversible and catastrophic consequences. Stemming the extent of warming at 1.5 degrees Celsius rather 2 degrees or worse will reduce the risk of crossing such tipping points or otherwise exceeding the adaptive capacity of human society. Every degree matters. Stabilizing global warming at 1.5 degrees Celsius starts with cutting annual greenhouse gas emissions in the United States to half of peak levels by 2030. This isn’t about temporary offsets or incremental gains in efficiency—it’s about the rapid adoption of scalable solutions that will work throughout the world to eliminate global net emissions by 2050 and sustain net-negative emissions thereafter. Building this better future will tackle climate change, deliver on environmental justice, and create good jobs. It will give us a shot to stop the planet from continuously warming. It will alleviate the concentrated burdens of fossil fuel pollution, which are concentrated in systemically disadvantaged, often majority Black and brown communities. It will empower American workers to compete in the global clean energy economy of the 21st century. There is no time to lose in the work of building a clean energy future.

## 2 – BioTech DA

#### Biotech industry strong now

Cancherini et al. 4/30 [(Laura, Engagement Manager @ McKinsey & Company, Joseph Lydon, Associate Partner @ McKinsey & Company, Jorge Santos Da Silva, Senior Partner at McKinsey & Company, and Alexandra Zemp, Partner at McKinsey & Company), “What’s ahead for biotech: Another wave or low tide?“, McKinsey & Company, 4-30-2021, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide] TDI

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6

What about SPACs?

The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story.

Fundamentals continue strong

When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances.

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have more than 250 vaccine candidates in their pipelines, along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries.

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the top dozen pharma companies having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic.

More innovation on the horizon

The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science.

#### Lack of IP protection makes medical innovation prohibitively risky and expensive

Grabowski et al 15 [(Henry, Professor of Economics, member of the faculty for the Health Sector Management Program, and Director of the Program in Pharmaceuticals and Health Economics at Duke University) “The Roles of Patents and Research And Development Incentives In Biopharmaceutical Innovation,” Health Affairs, 2/2015] JL

The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term.

Several economic characteristics make patents and intellectual property protection particularly important to innovation incentives for the biopharmaceutical industry. **5** The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a billion dollars in out-of-pocket costs. **6** Only approximately one in eight drug candidates survive clinical testing. **6**

As a result of the high risks of failure and the high costs, research and development must be funded by the few successful, on-market products (the top quintile of marketed products provide the dominant share of R&D returns). **7**,**8** Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market.

Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents.

New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment.

Patents play an essential role in the economic “ecosystem” of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. **11** The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms.

#### IP enables critical information sharing

Simon 6/25 [(Brenda, professor at California Western School of Law, research interests focus on how technological developments affect intellectual property and information law, former teaching fellow for the Law, Science and Technology LL.M. Program at Stanford Law School, and a research fellow in the Stanford Center for Law and the Biosciences, JD from UC Berkeley School of Law) “Patents, Information, and Innovation,” Brooklyn Law Review, 6/25/2020] JL

Patents play numerous roles in encouraging the exchange of information during the investment-seeking process in the medical device industry. One role is reducing the likelihood that the medical device will be expropriated. The risks of expropriation at this stage vary depending on the circumstances, which were set forth from a theoretical perspective in Part I and will be contextualized with examples from the medical device industry in this Part. Some of the variables in assessing expropriation risks, and consequently the function of patents in enabling information exchange, include whether the medical device is self-disclosing and easily reverse engineered, the importance of reputational and industry norms, and whether staging disclosure over time is an option.222 Time and resource constraints may limit the efficacy of some of these alternative mechanisms to patents in mitigating the risks of expropriation.223

Apart from their ability to ensure exclusivity, patents have an independent function of providing a useful signal to investors about information distinct from the medical device invention, such as resource allocation and the experience of the executive team, similar to their role in the biotechnology industry.224 An issued patent can also provide an indication about the viability of the invention, such as the ability to limit competition, extend the first mover advantage, and provide an independent source of value to the company through licensing or sale.225

One survey of twenty venture capital fund managers looked at the importance of intellectual property protection in assessing the risk-return ratio of portfolio companies .226 For medical device companies, respondents ranked intellectual property protection third, after reimbursement and regulatory concerns at the FDA.227 The authors of the survey reasoned that intellectual property protection was a concern of venture fund managers, given the high patenting rates among venture-backed companies and that the size of medical device companies necessitated "their reliance on patent protection to maintain barriers to market entry by competitors ."228 Additionally, court decisions that cast doubt on whether patent protection would be available for some medical devices have also raised concerns.229

#### MRNA solves a litany of diseases, but continued innovation is key

Gupta 5/7 [(Swati, vice president and head of emerging infectious diseases and scientific strategy at IAVI, a nonprofit scientific research organization that develops vaccines and antibodies for HIV, tuberculosis, emerging infectious diseases (including COVID-19) and neglected diseases, PhD and MPH from Yale University) “The Application and Future Potential of mRNA Vaccines,” Yale School of Public Health, 5/7/2021] JL

The implications of mRNA technology are staggering. Several vaccine developers are studying this technology for deployment against rabies, influenza, Zika, HIV and cancer, as well as for veterinary purposes. Its potential utility is based upon its being a “platform technology” that can be developed and scaled rapidly. Given that only the genetic code for a protein of interest is needed, synthetically produced mRNA vaccines can be made rapidly, in days. Other vaccine approaches involve growing and/or producing proteins in cells, a process that can take months. Messenger RNA vaccines are generally regarded as safe, since they do not integrate into our cells’ DNA and naturally degrade in the body after injection. They also can be safely administered repeatedly, as we are seeing with the two-dose regimen for both the Pfizer-BioNTech and Moderna vaccines.

Despite the current success of mRNA vaccines for COVID-19, scientists continue to work on making the technology better. A number of laboratories are testing more thermostable formulations of mRNA vaccines, which currently must be kept at freezing or ultra-cold temperatures. Others are investigating second-generation vaccines that will only require a single shot, and “universal” coronavirus vaccines that could protect against future emerging coronaviruses. Messenger RNA vaccines that target a broad range of different diseases, all in one shot, are also in development; this approach has the potential to greatly simplify current vaccination schedules.

Taken together, these advantages and potential future developments position mRNA vaccines as an increasingly important technology in our arsenal of tools against infectious disease outbreaks, and are likely to be critical to fighting future epidemics and pandemics. Global partnerships like the Coalition for Epidemic Preparedness and Innovation (CEPI), tasked with facilitating the development of vaccines to stop future epidemics, have called for vaccines to be able to be tested in the clinic within months after a new pathogen is identified. With the latest discoveries in mRNA technology, we are well on our way to this goal; the ability of this platform technology to be transformative is no longer a hope, but more likely to be a reality in the very near future.

#### Disease causes extinction – defense is wrong

Piers Millett 17, Consultant for the World Health Organization, PhD in International Relations and Affairs, University of Bradford, Andrew Snyder-Beattie, “Existential Risk and Cost-Effective Biosecurity”, Health Security, Vol 15(4), http://online.liebertpub.com/doi/pdfplus/10.1089/hs.2017.0028

Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world’s population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization.

A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity’s favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6

While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and theWestern Abenaki (which suffered a staggering 98% loss of population).

In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-2