

# **VACCINE POLICY PERSPECTIVES: MARKET STRATEGIES**

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## Vaccine Policy Perspectives: Market Strategies

Options for improving the financing of vaccines through market-based approaches that could strengthen production, competition, and purchaser practices, such as using price incentives to increase supply, using a voucher system to distribute vaccines, decreasing patent controls to improve competition, or reducing barriers to global competition in the U.S. strengthening the demand for vaccine products.

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## Introduction

There is ample evidence that the U.S. vaccine market is not working well. During the past 20 years, the number of major vaccine producers has dropped from dozens to five worldwide (Mercer 2002). The number of US-licensed vaccines has dropped from 380 in 1967 to a few dozen today (Miller, August 2002). Critical childhood vaccines are being made either by a single producer or a small subset of manufacturers. Disruptions in vaccine production due to regulatory shutdowns, liability concerns, plant re-tooling and post-production distribution glitches have caused the discontinuation of adenovirus vaccine, unforeseen shortages of flu vaccines and pneumococcal conjugate vaccine, and distribution disruptions for several critical childhood vaccines in the past few years (Weschler, 2002; Serafini, 2001).

On the consumer side, while it is theoretically possible for any child residing in the United States to get age-appropriate vaccination without charge, there is a bewildering mishmash of federal, state and local governmental public programs with varying degrees of responsibility for ensuring vaccination compliance; and a similarly incoherent patchwork of private non-profit and for-profit health care finance and delivery organizations also tasked with vaccination responsibilities. As a consequence, it is estimated that only 74% percent of American children receive the full complement of age-appropriate vaccine doses, and those at highest risk of disease are least likely to be fully vaccinated (CDC MMWR Aug, 2002).

At a time when bioterrorism is no longer just a theoretical possibility, new infectious agents like the West Nile virus can be unwittingly jetted around the planet in an instant, and devastating nemeses like tuberculosis and pneumonia, once thought essentially conquered, are reappearing as drug-resistant super-bugs, it is vitally important that the U.S. and the world have a vigorous and expanding vaccine R&D and production capacity.

Instead, the federal government shut down its vaccine production facility in the mid-1990s (Cohen and Marshall, 2002), and after centuries of state-level public involvement in vaccine development and production, Michigan sold the last state vaccine laboratory in 1998 (Poulson and Kellogg 1998). The total estimated vaccine R&D spending of the five multinational vaccine manufacturers was \$750 million in 2000 (Mercer, 2002). This represents only 2.9% of the 2000 pharmaceutical R&D expenditures for all PhRMA member companies (PhRMAa 2002) and 0.6% of U.S. drug expenditures in 2000. While PhRMA member companies spend more than 20% of pharmaceutical revenue on drug R&D, they spend only 12% of vaccine revenue on vaccine R&D (PhRMA 2002a; Mercer 2002).<sup>1</sup>

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<sup>1</sup> Vaccine development time-to-approval lags are also expected to increase (Kaitlin, 2002). PhRMA (2002b) reports that member company R&D spending on biologicals (including vaccines) dropped from \$805.9 million (4.4% of total R&D expenditures) in 1999 to \$664.5 million (3.1% of total R&D expenditures) in 2000.

In this paper, we will evaluate both demand and supply side aspects of the U.S. vaccine market that impede competition, innovation and technological change in vaccine production, and age-appropriate vaccination coverage of target population groups.

## Supply Side Issues

There is discussion in the vaccine market literature as to whether vaccine market segmentation is an indicator of product differentiation, price discrimination or bilateral bargaining between monopoly producers and government monopsony purchasers, and whether the CDC should use one strategy or another to extract the greatest price discounts from monopoly manufacturers and to maintain strategic stockpiles to overcome vaccine supply disruptions (Pauly et al. eds, 1996). All of this begs the question as to why the U.S. vaccine market appears moribund and non-competitive.

The inability of the pharmaceutical industry to maintain the same pace of vaccine R&D and new product development as it has with non-vaccine pharmaceutical products has numerous explanations, but can be illustrated quite simply when one looks at the relative profitability of vaccines and other medications (Rappuoli et al. 2002). A unique characteristic of successful vaccines, particularly in comparison to chronic disease medications is that they are rarely used. Instead of generating daily lifetime utilization and revenue, vaccines are typically used once a year, decade or lifetime.

The cost of vaccination research and development is not well-characterized in the literature, but it is probably similar to other pharmaceutical products. Vaccine manufacturing costs, by nature of the biological processes involved, are typically higher than other pharmaceutical manufacturing costs (Mowery and Mitchell 1995, 1996). Anecdotal evidence suggests that vaccine development costs are also higher than those for other pharmaceutical products, since the FDA imposes a higher safety standard on products that will be administered to large numbers of disease-free or symptom-free individuals in order to prevent disease (Crawford 2002).<sup>2</sup>

The most recent estimate of the total amortized costs of bringing a single new pharmaceutical to market is \$802 million (DiMasi 2001). While this estimate has generated some controversy, it is within the plausible range. For simplicity, assume that the cost of developing a new vaccine is \$1 billion amortized to the date of FDA marketing approval. Effective pharmaceutical patent protection generally lasts about 12 years from time of market approval to time of patent expiration (DiMasi 2001) but competition from therapeutically-similar branded products has accelerated in the past two decades and has rapidly reduced the time-window during which an innovative drug is able to use its patent protection to command a monopoly market position (PhRMA 2002).

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<sup>2</sup> This is particularly true when the vaccine target population is young infants. As an example, the latest combination (DTaP, Hep B, IPV, Hib), pediatric vaccines in development have required much larger safety and efficacy studies than the original single-component studies, since the regulatory authorities are concerned about the potential stability and potency of each of the components in the multi-component product. The number of pairwise safety/efficacy comparisons increases exponentially with the number of vaccine components tested.

It is probably reasonable to assume that the bulk of vaccine profits must be earned in the first five years after FDA marketing approval.

For any pharmaceutical product to cover the average \$1 billion amortized development costs, and generate a competitive pre-tax gross return on investment, pharmaceutical company shareholders would expect a present-value sales forecast at time of product launch of at least \$1.2 billion (net of all product production, marketing and sales costs). If the product's profit window is expected to be about five years, this means minimum annual product sales revenues of \$300 million are needed, depending on costs of capital and projected market risks.

If the new pharmaceutical product (not a vaccine) were used daily by one million chronic disease patients, a price of \$1 per day plus manufacturing and marketing costs would generate an acceptable return on investment. If the new product is a childhood vaccine, and is used by an entire cohort of 4 million U.S. newborns, a price of \$75 per patient per year (plus manufacturing and marketing costs) would be needed to generate an acceptable financial return. Few vaccines achieve 100 % population coverage, and government vaccine purchasers (e.g., the CDC which purchases about half of U.S. childhood vaccines) demand steep discounts from list price. Foreign vaccine purchasers, almost uniformly government authorities, also demand steep discounts from list price. As a consequence, to generate an adequate return on pharmaceutical investment the U.S. private-pay vaccine revenue must exceed \$100 per child per year (plus manufacturing and marketing costs).<sup>3</sup> Vaccine purchasers and health insurers have resisted such price levels as exorbitant.

However, for a vaccine to achieve the same "blockbuster" status as the top-selling drugs that excite pharmaceutical company shareholders and financial analysts, it would have to achieve price targets an order of magnitude higher than this resistance level. The three top vaccines generated \$1.7 billion (28% of total vaccine revenue) in global 2000 revenue (Mercer, 2002). The three top pharmaceutical products generated \$10.6 billion (9% of total) in 2000 U.S. revenue (Drugtopics.com 2002) and closer to double that in worldwide revenue.<sup>4</sup> Since vaccines cost the same or more to develop and manufacture as other pharmaceutical products, and generate only a small fraction of non-vaccine pharmaceutical product revenues, it is not surprising that pharmaceutical and biotechnology manufacturers focus their limited R&D resources on innovative daily treatments for chronic diseases.

It is ironic that CDC and other government (U.S. and foreign) purchasers use their monopsony power to capture steep pricing discounts from vaccine manufacturers (Rappuoli et al. 2002). Optimal government policy should subsidize vaccine production, not tax it. Even if vaccine manufacturers received full market price on every dose sold vaccines would still remain socially undervalued (Kremer 2000a). This is because unlike

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<sup>3</sup> High income countries (North America, Japan, Europe) represent 12% of vaccination volume, but 82% of vaccine revenue (Mercer 2002).

<sup>4</sup> Top 3 vaccines sales revenue in 2000: pneumococcal conjugate, meningococcal conjugate, varicella; top 3 U.S. drug sales revenue in 2000: omeprazole, atorvastatin, lansoprazole.

most other pharmaceutical products, vaccines have large positive consumption externalities.<sup>5</sup> When an individual is vaccinated against infectious disease the benefits accrue not only to the person inoculated, but also to all of those who otherwise would have been infected by that person (either directly or indirectly). Private market vaccine prices only account for private demand, and thus undervalue vaccines. This is true not only for specific vaccines, but also for the socially optimal level of vaccine R&D and production capacity.

### *Vaccines and Intellectual Property Rights*

It has been argued that since most vaccines are mature products and many vaccine patents have expired long ago, the role of patents in protecting and stimulating vaccine R&D has little relevance. Given the rapid pace of biomedical research over the recent past and foreseeable future, this is akin to arguing that reductions in new patents for vacuum tube transistors or VHS videotape technology indicate stable and healthy industries. The slow pace of safer, more convenient and more efficacious vaccines for those childhood diseases already covered, and for newer pathogen targets is directly related to unfavorable private sector risk-reward calculations for risky vaccine R&D.

Under law and public policy vaccines are treated like any other pharmaceutical product in terms of intellectual property rights protection. Patents are awarded to the individual or firm who establishes legal proof of original discovery. The patents generally prohibit anyone but the patent-holder to market the vaccine for a period of twenty years from the patent award date. Because developing safety and efficacy evidence for the (FDA) regulatory approval process can take many years, the effective period of pharmaceutical patent protection is generally reduced to somewhat more than a decade (DiMasi 2001).<sup>6</sup>

Looking across the entire economy, patents generally do a good job of simultaneously solving two problems in stimulating R&D for new goods and services. With a guaranteed period of market exclusivity, the patent-holder can capture monopoly profits that subsidize the research and development costs needed to obtain the patent, and more importantly in the case of pharmaceuticals, overcoming the expensive safety and efficacy regulatory hurdles. Absent patent protection, competitors would simply imitate or reverse-engineer the product without paying for the original R&D costs, and charge marginal cost pricing shortly after the time of marketing approval, eroding the originator's profits. This would substantially diminish the incentives for anyone to originate new products. Moreover, under the patent system the monopolist is rewarded profits in the market that are roughly proportional to market demand and societal willingness to pay.<sup>7</sup> This solves the other problem in rewarding innovation; how does the government or the public determine or monitor what the patent is actually worth?

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<sup>5</sup> Positive consumption externalities are benefits that accrue to consumers other than those actually purchasing the commodity (Henderson and Quandt 1990).

<sup>6</sup> To encourage the marketing of drugs that may have been patented long before potential FDA approval, the 1984 Hatch Waxman Act guarantees a minimum of five years of exclusive marketing to the patent-holder for FDA-approved pharmaceuticals.

<sup>7</sup> Particularly for vaccines and other relatively demand-inelastic constant marginal cost medical products.

The use of patents to stimulate the development of new intellectual property in the medical field leaves ample room for improvement (Hay and Yu 1999; 2000). Patented inventions (e.g. a future cure for cancer) are doled out with incorrect pricing signals and with the dead-weight loss associated with monopoly pricing. Large numbers of patients who would be willing to pay more than the marginal cost of production for the patented medical product, but who can't afford the monopoly price are unable to obtain what are literally life-saving interventions. This perceived injustice has led to domestic and international political friction by pitting the legal patent-holders, usually large multinational pharmaceutical corporations, against dying AIDS patients in America or Africa (Kremer 2000b), or against governmental mandates to protect their populations from bioterrorism through, for example, immediate emergency acquisition of ciprofloxacin or smallpox vaccines (Nader and Love, 2001).

The irony, not lost on pharmaceutical and vaccine producers, is that if they invent something really fantastic, it may be completely expropriated by politicians and government agencies in the name of helping suffering patients or frightened citizens. This further diminishes the effectiveness of patents in stimulating new pharmaceutical and vaccine invention. Moreover, patent rewards for innovation steer private-sector investors to develop only patentable medical products, and to test them only to the point of marketing approval. In the medical field, the societal cost is enormous for not adequately investigating unpatentable products, products after the marketing approval date or after the patent has expired (Hay and Yu, 1999, 2000).<sup>8</sup>

An under-remarked additional problem with monopoly patent rewards that is particularly relevant to the vaccine market is that in addition to creating the Econ 101 textbook monopoly pricing distortions, a monopoly producer, like the old Soviet Gosplan Commissar has no competitive incentive to guarantee timely, high quality product. Vaccine production is technically complex. Having the belt and suspenders of the FDA and the tort liability legal system to monitor quality can yank the monopolist to attention, but can never push timeliness and production efficiency as well as market competition. When a supply problem like documenting vaccine manufacturing lot quality or removing thimerosal preservative is identified by lawyers and/or regulators, the monopolist producer will choose a route and timeframe to solve the problem that may be optimal for the company's shareholders, but not for a society suffering vaccine shortages.<sup>9</sup> The regulators and the public have to just sit and wait.

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<sup>8</sup> A brief list of examples will illustrate this fact. Because the patents have either expired or are difficult to obtain or enforce, there has been a suboptimal investment in behavioral interventions to lower the risk of AIDS and STD transmission; behavioral therapy for mental health; aspirin, ACE inhibitors and beta blockers for cardiovascular protection; cheap antibiotics to prevent ulcers; or rigorous evaluation of the medical claims for complementary and alternative medicines. Many patented products also slip through the FDA approval system based on short term clinical studies in small homogeneous populations only to generate enormous social costs because there are few private-sector incentives to evaluate them once on the market. These have included rotavirus vaccine, hormone replacement therapy, troglitazone, seldane, hismanal, fen-phen (fenfluramine and dexfenfluramine), clofibrate, eccanide, fleccanide and many others.

<sup>9</sup> Moreover, when multiple firms are competing in the same vaccine market, society is not as vulnerable to a plant shut down for a specific quality problem. Different firms may use slightly different solutions to

Vaccines have the dual public goods characteristics of intellectual property innovation in development, and positive externalities in consumption.<sup>10</sup> It is hard to think of human inventions other than fire and the wheel with greater positive public goods characteristics than Edward Jenner's first smallpox vaccine in 1796. So why not make vaccines full-fledged public goods, funded and produced by government?<sup>11</sup> The public goods aspect of vaccine development can only be enhanced as future technologies allow the creation of gene-based delivery systems that will spread vaccines through food, water, or even through public release of infectious respiratory viruses altered to confer disease immunity rather than illness. As these future genetic technologies are explored and safely developed by scientists, attempts will inevitably be made by terrorists to exploit them. It will be a matter of the highest national security to have effective vaccine countermeasures one or more steps ahead of the terrorists. In the Vaccine Supply Solutions section below, we discuss the issues related to expanding the governmental role in vaccine production capacity.

Schemes to reward or otherwise encourage the development of intellectual property, specifically in the vaccine marketplace have been characterized as either "push" or "pull" programs (Kremer 2000a). Push programs involve the use of public resources to build research programs either in government agencies, academic institutions or other organizations for basic or applied vaccine research. Generally these programs involve cost-based, performance-incentives, or fixed fee contracts for achievement of specific R&D milestones. An advantage of most push programs is that the government usually requires that intellectual property rights to funded innovation be immediately placed in the public domain. A disadvantage of push programs is that public funds are spent, whether or not the public objectives are achieved. Pull programs involve the use of public resources to reward the developer *only* after the project is successfully completed. Patents are one example of a pull program. Other pull program examples include government prizes, pre-announced government purchase commitments, patent buy-outs or side-payments (Kremer 2000a).

Alternatives to the simple "push" contract research award and the "pull" patent can easily become overly complex, difficult to monitor, and subject to non-productive gaming or rent-seeking behavior by the participants. In the vaccine marketplace, many of these issues are more easily dealt with than in the general economy.<sup>12</sup> Several alternatives to

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quality control, manufacturing and ingredient formulation tasks. The regulator can monitor these differences and use the variations to standardize on best practices where necessary. With one monopoly producer, everything is non-standard.

<sup>10</sup> Public goods are commodities or services for which consumption by one consumer does not exclude and cannot prevent consumption by another consumer (Henderson and Quandt, 1990). Examples would include scenic vistas, clean air and water, law enforcement, and military defense.

<sup>11</sup> The federal government is already substantially involved in vaccine research through various programs at the Centers for Disease Control and the National Institutes of Health ([www.dhhs.gov](http://www.dhhs.gov)). Additional public sector vaccine research occurs in academic institutions and other state and local agencies.

<sup>12</sup> It is much easier to assess the optimal societal reward size for development of a flu vaccine than a ginzu steak knife, a clean efficient internal combustion engine, or a faster computer chip. Conversely, items that don't require regulatory oversight, or that consumers can be made familiar with are best rewarded through marketing patents.

the current patent system have the potential to improve the vaccine marketplace without damaging private sector incentives to profit from vaccine innovation. Michael Kremer and his co-authors have made substantial contributions to developing alternative R&D incentive systems for vaccine markets (Kremer 2000b). These will be discussed in the Vaccine Supply Solutions section below.

### *Vaccine Regulation*

Not all of the impediments to a vibrant competitive vaccine market result from the patent system (Arnould and DeBrock 1966). In fact, several of the vaccines required for childhood immunization have been able to maintain monopoly markets long after patent expiration. One could however argue that lack of progress in replacing these old technology vaccines with safer, more effective, more stable and more simply administered vaccines is symptomatic of a vaccine market where R&D is not as healthy as it should be.

Unlike most pharmaceuticals, which are manufactured with relatively standardized chemical engineering processes, vaccine-manufacturing steps involve the complex transformation of live biologic organisms into pure, active, safe and stable immunological components. Highly sterile temperature-controlled environments are needed at each manufacturing step. FDA-approved vaccines are subject to rigorous, pervasive and costly quality inspection and review procedures. Even if a pharmaceutical manufacturer wanted to enter the market for a specific vaccine, construction of FDA-approved vaccine production facilities could take 2-6 years and potentially cost hundreds of millions of dollars. Some vaccine ingredients are harder to obtain than the secret recipe for Coca-Cola. Sing and Willian (1996) report that for many years Merck was the only domestic producer of MMR (measles, mumps, rubella) vaccine because it had the best mumps strain for use in MMR vaccine production.<sup>13</sup>

The regulatory barriers for entry to the vaccine marketplace are substantial and certainly protect market incumbents from those seeking market entry. For example, even in pre-marketing clinical trials, the FDA will only review vaccine production lots that are manufactured in a facility that has been approved by the FDA as meeting Good Manufacturing Practices (GMP) (Mowery and Mitchell 1996). It is a steep hurdle to ask a potential market entrant to build a complete vaccine manufacturing facility and get it GMP-approved by the FDA just to crank out a few vaccine lots for risky clinical trial testing. What do they do with the facility if the vaccine fails clinical trials? Existing vaccine market incumbents would be irrational to assist the potential market newcomer by turning over their own production facilities for these customized test-production lots.

### *Vaccine Manufacturer Liability Risks*

Another issue, often pointed to in the past by pharmaceutical manufacturers as impeding development of new vaccines, and in leading many of them to exit from the vaccine

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<sup>13</sup> It is not clear what public purpose is served by granting indefinite private ownership to valuable pathogen genotypes.

marketplace was the apparently open-ended liability risk exposure they experienced merely by selling childhood vaccines approved by the FDA for safety and efficacy, officially recommended by expert medical committees, and required by state law for child school attendance. The vaccine damages litigation probably hit a high watermark with the 1986 Johnson vs. American Cyanamid polio vaccine case where the plaintiffs were awarded \$10 million; including \$8 million in punitive damages (Ridgway, 1999).

In 1986 the National Childhood Vaccine Injury Act was enacted. This law established a no-fault damage award system, whereby eligible patients showing damages from routine childhood vaccine administration would receive standardized and limited compensation as determined by Special Masters of the Court of Federal Claims.<sup>14</sup> Vaccine manufacturers and health care providers were protected from these vaccine damage claims. The cost of compensating these claims was funded through an excise tax attached to unit sales for recommended childhood vaccines. The excise taxes per vaccine dose were based on the perceived risks associated with different vaccines, and range from \$5 for DTP to \$0.29 for OPV to \$0.00 for Hib and HBV (Sing and Willian 1996).

The National Childhood Vaccine Injury Act appears to have worked quite well to resolve the liability concerns of vaccine manufacturers and health care providers. After an initial period of adjudicating a large backlog of claims that had developed prior to the law's enactment, the number of new compensation cases has dropped substantially. The compensation fund has been adequate to deal with the damage awards, and new vaccines, including varicella and DTaP have been added to the list of covered vaccines. Ridgway (1999) concludes that the no-fault compensation approach to vaccine damage compensation is successful enough to be recommended as a model for other areas of damage litigation resolution, such as toxic substance exposure.

However, newer potential vaccine liability scares have developed. Trial lawyers have taken on thimerosal preservative as a vaccine manufacturer liability target (Wechsler 2002), arguing that National Childhood Vaccine Injury Act protection for active vaccine ingredients does not apply to vaccine preservatives or presumably anything else about the vaccine that isn't specifically covered. This issue was short-circuited by the recently-passed Homeland Security Act which includes coverage of alleged thimerosal injuries under the vaccine compensation fund (Frist 2002). Rotashield, the first vaccine against rotavirus was pulled off of the market by Wyeth Lederle several months after FDA marketing approval because of rare potentially serious cases of intussusception. This unexpected result occurring so quickly after product licensing has raised concerns among vaccine developers and regulators. It has led to increased vaccine clinical trial sample size calculations and corresponding higher clinical development costs.

## **Vaccine Delivery Issues**

Many children in the US do not receive vaccines, and many are not immunized at the appropriate time (CDC MMWR Aug, 2002)). This population is more likely to be poor,

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<sup>14</sup> There has long been controversy regarding conflicts between scientific evidentiary standards to prove damages versus legal evidentiary standards to prove damages (Fumento 1993; Angell 1996).

uneducated, difficult to reach, or otherwise disadvantaged. Solutions to improve the efficiency of delivering vaccines should particularly be targeted at these underserved populations.

Baseline disease occurrence rates for 1998 and target rates for 2010 are well laid out, and discussed, in the context of preventing disease, disability and death from vaccine-preventable diseases (Healthy People 2010, CDC, 2000). This report summarizes the major strategies to protect people from vaccine-preventable diseases (CDC MMWR Feb, 1994) to revolve around improving the quality and quantity of vaccine delivery services and vaccine use, minimizing financial burdens, increasing community participation and education and improving the monitoring systems of immunization levels and disease.

Intervention strategies for improving immunization coverage in children, adolescents and adults have been extensively explored by the Task Force on Community Preventive Services (CDC MMWR June, 1999; Guide to Community Preventive Services, 2000; Briss, et.al., 2000; Shefer, et.al., 1999). Interventions were stratified according to whether they increased community demand, enhanced access or were provider-based, and reviewed as to their effectiveness, applicability, economic evaluation and ease of implementation.

### *Barriers to Immunization*

#### Financial Barriers

Vaccines are purchase on a two-tiered pricing scheme. The CDC purchases reduced-price vaccines through federally negotiated contracts with the manufacturer, while private providers purchase vaccines at the catalog price (up to twice as expensive). The total amount of vaccine purchased in the US is approximately evenly distributed over the two sectors. States have two options for purchase of vaccines:

1. They can either define children as “state vaccine-eligible” and purchase vaccine at federally contracted reduced prices. Any subcontracts drawn up with insurers must not include payment for vaccine costs, although any costs associated with vaccine administration may be included.
2. States may contract with insurers for the provision of vaccine to underserved populations, as they do for other services. In this case, private-sector prices for vaccines must be paid.

At the federal level, the Vaccines For Children (VFC) program currently enables the CDC to buy vaccine at federally discounted prices. Federally vaccine-eligible children under this program include the uninsured, Medicaid-eligible, American Indian and Alaskan Native children, and the underinsured, i.e. children whose health insurance does not cover vaccination.

At a state level, financially disadvantaged children are vaccinated either through the VFC program (1993), or else through SCHIP (1998), that state’s Children’s Health Insurance

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Access problems

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Besides financial barriers, some populations face a low educational level and time / transportation issues that prevent adequate access to immunization.¶  
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Program (Miller, 2000). Under CHIP, immunization must be furnished according to the recommendations of the Advisory Committee on Immunization Practices (ACIP). States that have designed a separate state CHIP (SCHIP) may not treat children enrolled in SCHIP as federally vaccine eligible. In this case, children within a SCHIP are neither Medicaid-eligible, nor is their immunization necessarily covered by insurance.

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Any vaccine support program must consider the level of reimbursement to providers in order to be effective at promoting immunization delivery. States can also consider additional financial incentives for plans that perform well, and financial penalties for plans that do not show acceptable utilization rates for preventive services and immunization (Wood and Halfon, 1996).

### Low Educational / Socioeconomic Status

Once the vaccine shortage problem is solved and the immunization delivery options are clarified, there still remains the problem of having the child physically immunized.

Besides financial barriers, disadvantaged populations face other constraints that prevent adequate access to immunization. For example, a working mother without health insurance takes unpaid time off work to bring her child to her MCO family-practice physician. The physician may recommend vaccination, but rather than provide it in that setting, refers the mother to the state health department for free vaccination, because she does not have insurance coverage for immunization. The child would leave the clinic unvaccinated, and would either not be vaccinated at all, or be vaccinated later than recommended, because it may be difficult for the mother to take more time off work, or find someone to take the child in her place.

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Other scenarios also contribute to lower vaccination rates.

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Risk-factors associated with inadequate immunization rates include minority group status, poverty, inadequate pre-natal care, inner-city neighborhoods and being uninsured (Guyer et.al., 1994; Kum-Nji et.al., 1995; Wood et.al., 1995; Newacheck et.al., 1996; Bates and Wolinsky, 1998; Santoli et.al., 2000; Shaheen et.al., 2000).

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Community Demand and Provider-induced Demand¶  
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A lack of knowledge of the interplay of funding and access systems decreases the probability that children will receive consistent, continuous care.

### Lack of information about vaccine delivery

A lack of knowledge of the interplay of funding and access systems decreases the probability that children will receive consistent, continuous care. Although all of these options for vaccine delivery may enhance the possibility of a child getting vaccinated, they are befuddling and complex. Their interplay may also result in some segments of the population “slipping” through the system and not getting immunized properly. Current inner-city vaccination rates for the 4:3:1:3:3 series are not as high as would be desired by public health officials. National coverage with combined vaccination series 4:3:1:3 and 4:3:1:3:3 decreased from 1999 to 2000: 78.4% to 76.2% and 73.2% to 72.8% respectively (CDC MMWR, 2001).

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It may also be the case that vaccination schedules are not as well known in detail, by both health care practitioners and the general public, as would be necessary for optimal immunization rates. Lack of information may be one of the factors underlying the general

perceptions of vaccines across the public at large, leading to a lack of awareness for how valuable and cost-beneficial they are.

### *Monitoring systems*

It also is hard to track and maintain records of vaccinations. This complicates the determination of an immunization rate *per se*. It also makes it difficult to verify the immunization status and needs of each child, contributing to the probability that the child is not vaccinated on time. Ironically many vaccinated children with inadequate immunization records may get unnecessary redundant vaccines at the time of school entrance so as to comply with school immunization records requirements.

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Deleted: Across the public at large there certainly exists an undervaluing of vaccines and a lack of awareness for how valuable and cost-beneficial they are.¶

The public health infrastructure that would enable the maintenance of a vaccination registry, the basic step towards any recall/reminder system, is inadequate. Providers often work within a bureaucracy and have very little incentive to increase vaccination rates.

## **Vaccine Market Solutions**

We will present a number of potential policy changes designed to improve the U.S. vaccine market. While we have our preferences among these recommendations, it is more important in this context to identify the positive and negative components of each approach rather than narrowly advocate one approach over others. It should be noted that these ideas are not necessarily original nor are they substitutes for each other. Some combination of these ideas may be preferable to any one approach in isolation. Moreover, we have made no attempt to factor in political barriers to implementation of these recommendations, or to rate them on a feasibility basis.

In the Vaccine Supply Solutions Section below, we will outline market-oriented approaches to enhancing the national vaccine R&D and production capacity, and of ensuring supply of important childhood and other vaccines. In the Vaccine Demand Solutions Section below we will outline a number of potential market-oriented solutions that may work alone, or in combination, to improve the delivery and administration of vaccine to children, especially those in underserved populations. We also highlight previously suggested/studied interventions, whose implementation may prove to be critical to the success of any market-oriented solution.

## **Vaccine Supply Solutions**

### *1. Public sector solutions*

There is a long tradition of American vaccine R&D and production at both the state and federal levels co-existing with private vaccine firms. Unfortunately these public facilities have experienced attrition even worse than that in the private sector. Currently, outside of the U.S. military, there are no remaining public vaccine production facilities in the

U.S. Public sector vaccine R&D and production facilities and projects can enhance the private vaccine sector through open sharing of ideas and methods.<sup>15</sup>

The Institute of Medicine (IOM 2001) has recommended that a National Vaccine Authority (NVA) be established to assist private manufacturers in overcoming barriers to vaccine development and production, facilitate communication among vaccine researchers, examine vaccine liability issues, and help to reduce complexities and burdens in vaccine regulation. The NVA would also be tasked to develop and manufacture vaccines that could not be feasibly or profitably produced in the private sector but which are felt to be of sufficient national importance. Along similar lines, some have advocated funding of GOCO (Government-owned, contractor-operated) vaccine production facilities, specifically to provide vaccines needed by the military and for public health emergencies.

Given the public goods characteristics of vaccines, it is straightforward that an expanded government role has merit, particularly given the potential public health and bioterrorism threats that exist.

### **Plusses;**

The public sector can develop and/or produce what it deems to be high priority vaccines either for military or public health reasons independent of private sector vaccine development priorities. It would not be constrained to work on vaccine technologies with high private sector return on investment.

An enlightened NVA could actually stimulate the private sector vaccine industry by helping to solve some of the regulatory barriers to entry problems, quality assurance problems, and basic research issues that manufacturers face in vaccine development and production.

### **Minuses;**

An increased government presence, particularly on the vaccine production and distribution side of the vaccine industry may discourage private pharmaceutical and biotech firms from starting or sustaining investment in vaccine development and production. Based on prior history with US government support for international vaccines development (Kremer, 2002b), as well as experience with other public sector procurement histories, government vaccine production programs may not be efficient or effective.

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<sup>15</sup> There is substantial precedent for successful cooperation between federal government agencies, particularly the National Institutes of Health, and private firms to encourage development of new vaccines, including acellular pertussis, HIV, HCV and pandemic influenza vaccines (R. Rappuoli, personal communication; September 8, 2002).

Government programs designed to promote private industries and commercial interests are susceptible to cooptation by powerful special interests within those industries at the expense of smaller firms, newcomers and the general public.

Finally; government vaccines might not be held to the same product liability standards as private sector vaccines. If consumers experienced damage or injury from government vaccines the government would be in a conflicted role of both supplying the vaccine and making decisions on how much to compensate victims damaged by government vaccines.

## *2. Cash Rewards/Patent Buy-outs for New Vaccines*

We have suggested that the pharmaceutical industry under-provides new or enhanced vaccines because it isn't fully compensated for the positive externalities in vaccine development and use. Moreover, monopoly production and pricing introduce multiple levels of inefficiency and pricing distortion into vaccine use decisions. Kremer (1998, 2000a, 2000b) has argued the case of private-sector underprovision of vaccines for diseases like malaria, AIDS, tuberculosis, pneumococcus, and rotavirus in developing countries. A solution he has proposed is for governments to establish cash prizes, rewards, patent buy-outs or guaranteed government vaccine purchases payable to successful vaccine developers in return for putting the vaccine patent rights into the public domain, and thus allowing any vaccine manufacturer to competitively manufacture the vaccine.

Kremer shows the vaccine reward scheme to be a Pareto improvement over patent rewards in many circumstances. While Kremer has framed the reward program in terms of stimulating new patentable vaccines, there is no reason why a domestic U.S. vaccine market development program would have to be limited solely to improving incentives for this aspect of vaccine development. If a monopoly vaccine manufacturer had any inherent advantage keeping other manufacturers from entering the market beyond patents, rewards could be offered for overcoming these other barriers as well.<sup>16</sup>

Thus a reward could be offered for placing a proprietary vaccine manufacturing technique in the public domain. If the owner of this technique chose not to take the reward, there would be a strong financial incentive for other biotech and pharmaceutical manufacturers to innovate a technique that was as good or better than the original technique and claim the reward, meanwhile opening up competition in domestic vaccine supply. Similarly, if there were proprietary biologic strains that limited anyone except a monopoly producer for a specific vaccine, government cash rewards could either buy out the biologic strains or provide additional competitive inducements to create a public domain alternative.

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<sup>16</sup> Patent-holders and other monopolists rely on the social contract of property rights enforcement to maintain their profits. This social contract becomes frayed when these profits accrue at the expense of affordable medicines and avoidable deaths.

If anything, Kremer's proposal is more feasible as a solution to domestic U.S. vaccine development and production problems than it is in the international framework. The U.S. vaccine market is by far the most profitable in the world. If the U.S. government were to offer rewards or prizes for new or enhanced vaccines proportional to population willingness-to-pay (or similar in magnitude to the monopoly profits that the patent-holder or monopoly producer could otherwise earn in the U.S. market) U.S. rewards for placing patents in the public domain would be large enough to induce substantial expansion of vaccine R&D activity, while stimulating vigorous private-sector competition in vaccine production, independent of foreign country behavior. U.S. rewards could be offered in coordination with those from other countries, or, if other countries did not want to participate, patent-holders would retain traditional patent rights for pricing and marketing in foreign markets.

It should be noted that no change in law and no expropriation of private property is contemplated under this scheme. The government would simply announce specific cash rewards for new vaccines or for other new technologies that would alleviate monopoly vaccine production. The monopoly producer could either accept the reward and make the technology available to all competitors immediately, or wait for a competitor to innovate around their patent or barrier, and then lose their monopoly profits.<sup>17</sup>

Determining the size of the pre-announced vaccine rewards would not be technically difficult. There is a large domestic and international base of pharmaceutical cost effectiveness researchers ([www.ispor.org](http://www.ispor.org)). Guidelines for establishing the incremental cost effectiveness of new pharmaceutical products have been validated (Hay 1999; Chiou, Hay, Wallace et al. 2002). For each vaccine the government could convene an independent panel of experts to establish vaccine reward values based on marginal cost vaccine pricing and a societal perspective on vaccine costs and benefits.<sup>18</sup> Presumably the reward would be in line with (and certainly not exceed) what the monopoly producer reasonably anticipates in terms of future monopoly profits. The monopoly producer could do their own profit forecast calculation and decide to either accept the reward or pursue monopoly profits.<sup>19</sup>

The advantage of using this reward approach for vaccines (or pharmaceuticals) rather than other innovations is that there is a clear decision point at which the reward can be earned and paid. This is the point where the FDA determines that the vaccine is safe and effective in meeting a specific clinical indication for marketing approval. Should the

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<sup>17</sup> Standard economic theory says that lump sum transfers (taxes or rewards), not sales or excise transfers, provide the most efficient mechanism for eliminating monopoly pricing distortion.

<sup>18</sup> This would be similar to the Outside Expert Advisory Panels that the FDA convenes to make recommendations on vaccine and pharmaceutical safety and efficacy.

<sup>19</sup> Monopolists could always attempt to "hold-out" until just before a competitor developed a work-around innovation. To prevent this, rewards unclaimed by the monopolist would be downwardly adjusted annually after FDA marketing approval or the initial reward date. They would not be adjusted for potential competitors. This behavior is unlikely for vaccine manufacturers since, in addition to the cash, there would be substantial societal good will accruing to the public-spirited monopolist in making life-saving innovations publicly available. Should this turn into a serious real-world problem, the vaccine reward system could be augmented with a monopoly profits tax.

vaccine later turn out not to have the precise safety and efficacy characteristics established at time of FDA approval (e.g., rotavirus vaccine) the reward payments could be pro-rated based on new clinical evidence. The simplest way to accomplish this is to make the rewards payable over a multi-year period with outyear payments contingent on future knowledge.

**Plusses:**

Encourages private sector vaccine industry with multiple competitive suppliers, allows vaccines to be sold to all purchasers at marginal cost of production, encourages both vigorous R&D and vigorous manufacturing capacity.

**Minuses:**

Vaccine rewards could be susceptible to manipulation by political special interests in certain directions rather than others (e.g. breast cancer vaccines, not better childhood vaccines because kids don't vote). Most of the rewards for innovation would go to the first market entrant. This doesn't encourage minor improvements to follow-on competitive products, since the monopoly profits are immediately dissipated rather than gradually dissipated as in the current pharmaceutical patent reward environment. Finally, it is difficult for politicians to openly appropriate substantial government expenditures as "rewards" for medical innovation even where it can be firmly established that the implicit taxes imposed on society by a monopoly are larger.<sup>20</sup>

*3. Allow US adoption of any vaccine approved and/or manufactured under European or other international regulatory approval.*

It is not clear that the FDA should have a monopoly on Type I and Type II errors in drug approval and quality-assurance decision-making.<sup>21</sup> Certain novel vaccines (e.g., varicella, meningococcal C conjugate, tick-borne encephalitis, penta- and hexavalent pediatric combinations) are approved in the European Union, Canada or Japan years before they are approved in the U.S. and other competitive ("me-too") vaccines (e.g., DTaP) that would help to ease U.S. vaccine shortages and pricing concerns are also often not approved on the U.S. market for years after EU, Canadian or Japanese approvals. After the rotavirus recall experience, it is difficult for the FDA to assert that its vaccine regulatory procedures are inherently superior to those for all other regulatory agencies in the world.

It is also hard to claim that 500 million Europeans, Canadians and Japanese are systematically getting inferior vaccine approval decisions. There are certainly a host of issues that may require special FDA oversight and evaluation, ranging from

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<sup>20</sup> Kremer (2002) has suggested some alternative funding mechanisms more politically palatable than lump-sum rewards, including tax credits or guaranteed government purchasing commitments for successful innovative vaccines. These alternatives could also be applied to other monopoly barriers to entry.

<sup>21</sup> Type I error: Approving a drug in a timely manner that later turns out not to be safe and efficacious.  
Type II error: Failing to approve a drug in a timely manner that later turns out to be safe and efficacious.

immunogenicity characteristics for vaccines in particular American sub-populations to vaccine production quality standards. Nevertheless, it certainly makes sense to carefully consider ways in which FDA vaccine approval processes could be coordinated with those in other countries. These could include starting a time clock after EU, Canadian or Japanese approvals for the FDA to either make a decision on available evidence or detail the specific alternative studies needed before a decision can be made. They could also include establishing an outside panel of experts to do careful risk-benefit assessment of all FDA regulatory procedures for vaccine approval, marketing surveillance and production quality assurance. This latter proposal has been suggested as a function for the IOM-proposed National Vaccine Authority.

**Plusses:**

More vaccines available quicker at lower registration costs and lower production costs to manufacturers.

**Minuses:**

Potential reduction in regulatory oversight, some loss of U.S. policy influence on the vaccine market. Possible reductions in protectionist barriers to foreign vaccine competitors.

*4. Vaccine liability tort reform.*

It appears as though the National Childhood Vaccine Injury Act has been relatively successful in short-circuiting the liability risk concerns facing vaccine manufacturers and health care providers. It could be expanded to hold manufacturers harmless for unknowable or unproven damages associated with routine vaccines (e.g. the timerosal issue) or to add additional excise fees if such damages were established ex-post.

**Plusses;**

Reduces vaccine cost of development and manufacture, reduces manufacturer and health care provider risks.

**Minuses:**

Potential disincentive to manufacture vaccines as safely as possible.

**Vaccine Demand Solutions**

*Using Market Incentives to Improve Vaccine Delivery*

*1. County- or city-level contracts that are issued on a competitive basis to different public or private organizations to provide age-appropriate immunization and record-keeping for underserved communities.*

While many acknowledge that there is an immunization problem, and effective interventions have been studied and suggested, federal and state programs are hamstrung by existing laws and incentives. There is a lack of private competition for the delivery of vaccine to underserved children. This may contribute to stagnancy and a deficiency in efforts to maximize immunization rates to inner-city and rural underserved children.

Such competitive contracts would present incentives to providers or vaccine-delivery organizations to improve vaccination administration. The organizations could be paid a certain dollar-amount for each person who was vaccinated at the age-appropriate point, *AND* recorded in an official database, above and beyond the current baseline vaccination rate in that locale.<sup>22</sup> The dollar amount could include only the costs of administration, or also include the cost of the vaccine. Specific performance benchmarks could be the achievement of 4:3:1:3:3 underserved community immunization rates in the highest Xth-percentile, or increase in community vaccination rates in the highest Xth-percentile. With local organizations competitively bidding for contracts to deliver vaccine there would be a strong incentive to find the solutions that worked locally at the minimum cost. The competing organizations could be new or existing, public or private, or combinations and consortiums. The state health department, Managed Care Organizations (MCOs), private care practices and social work organizations would all be potential candidates for delivery provision.

**Plusses:**

Could potentially lead to higher numbers of children receiving all the age-appropriate vaccinations by two years of age (many schedules should be completed at this point), thus ensuring higher rates of compliance with the ACIP vaccination schedule. It may also sidetrack the issue of a child needing to be referred elsewhere for vaccination.

If the provider organizations are allowed to do anything they want (including possibly providing vouchers to end users) and are judged on their actual performance in boosting age-appropriate vaccinations, they will come up with original ideas and be flexible in overcoming local differences to achieve the targets.

In the case of managed care organizations participating in this system, an added incentive may be the wider patient base resulting from the increase in “Medicaid-Managed Care” patients that now enter a private health care delivery structure. This may also have tangential effects in improving the overall quality of care for Medicaid children and reduce the burden on potentially less efficient public clinics that may be a drain on community health care funds.

**Minuses:**

It may be difficult to ensure that children (parents/guardians) who would already be receiving privately delivered vaccine under the current systems, would not take advantage of solutions targeting underserved populations to get free vaccine. Contractors

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<sup>22</sup> Such incentives are offered to practitioners by the National Health Service in the UK.

would have to be monitored to ensure that increased vaccination and documentation rates were not artificially due to people who otherwise would have received vaccination elsewhere.

## 2. More vaccination in private practice primary care clinics

Deleted: and less referral for free vaccination to health state department.

Providers play a critical role, as parents tend to rely on them to take care of their child's immunization needs. The case for a "medical home" for a child has been made in various studies. By harnessing more of the private sector, vaccine-financing reforms may have contributed to substantially fewer vaccinations being administered in to health department clinics (HDCs), thereby keeping preschool children in their primary care medical homes (Szilagyi et.al., 2000a). Even in underprivileged communities, children who's primary health care provider was a private physician, or who were usually examined by the same physician, were more likely to be up-to-date with vaccinations within the first two years of their life (Bates and Wolinsky 1998).

More vaccination in private clinics would require providers to ensure a local supply of necessary vaccines and monitor their stocks closely. This, in itself, may improve the efficiency of vaccine market. Purchasers could enter into a sales-volume agreement with the vaccine distributor. The two-tier pricing system could be expanded into a three-tier one: the federally-negotiated discounted price, the catalog price, and an intermediate price negotiated by "vaccine-delivery organizations", which may have more bargaining power than a managed care organization, but less than the federal government.

Private/public partnerships can support this effort through the subsidization of vaccines for children brought to the physician in a private primary care setting, possibly through subsidization of private provider vaccine purchases. Less referral for free vaccination to health state department following the provision of vaccines to physicians has been well documented (Bordley, et.al., 1994; Fairbrother et.al.; 1997 Zimmerman et.al., 1997; 2001).

Provider- and/or practice-associated characteristics and/or interventions may be the most important determinants of the success of market-based delivery of immunization by private practice physicians (Taylor et.al., 1997a; Bordley et.al., 2001). Many interventions described in the Standards for Pediatric Immunization Practices (NVAC, 1993) have been shown to increase age-appropriate pediatric immunization rates with the 4:3:1:3:3 series. These include taking advantage of well-child and acute care visits to assess immunization status and administer relevant vaccinations, the implementation of aggressive reminder systems to notify parents when immunizations are due, administering all vaccines for which an infant is eligible at each health supervision visit, and improving provider knowledge of the immunization schedule and contraindications and therefore accepting fewer contraindications to vaccination (Orenstein and Bernier, 1994; Grabowsky et.al., 1996; Lieu et.al., 1996; Pierce et.al., 1996; Szilagyi et.al., 2000b; Minkovitz et.al., 2001; Taylor et.al., 2002).

## Incentives to physicians

Considering traditional forms of incentivizing physicians, fee-for-service payment incentivizes over treatment and increases the likelihood of vaccinations being administered over multiple visits. Capitation incentivizes under treatment. Neither approach ensures optimal vaccination strategies (Forgione et.al., 2000).

Various provider incentives have been shown to be effective in enhancing immunization levels among preschool children. The incentives provided to physicians included free vaccine, problem resolution and support regarding Medicaid billing, and physician education (Smith et.al., 1999). Clinic lead nurses also responded very well to financial incentives or in kind, such as gift coupons, plaques, dinner rewards, and attendance at conferences (Dietz et.al., 2000). Financial incentives have led to an increase in influenza immunization rates in the elderly (Kouides, et.al., 1998), but it is controversial whether financial incentives themselves are what cause the increase, as opposed to better documentation of immunization practices (Fairbrother et.al. 1999; 2001).

Each delivery practice would need to have incentives specifically tailored. Not all may have the same desired result. For example, increased surveillance of immunization rates and habits, together with peer review and feedback showed both an increase (Morrow et.al., 1995; Bond et.al., 2002) and no difference (Hillman et.al., 1999) in vaccination rates.

#### Plusses:

Financial incentives can improve compliance with practice guidelines. Less referral to public health clinics will decreases the loss of immunization due to inability of the parent/guardian to follow up. Ensuring physician vaccine supply implies that providers will always have vaccines on hand when required. Vaccine timing may not be perfect, but probably is still within the general time frame that immunizations should occur. Greater provider contacts will ensure higher vaccination rates and enhanced well baby care.

#### Minuses:

More vaccination in private clinics could overlap services with the public health clinics currently serving inner-city and other underserved children. Requiring providers to maintain adequate vaccine supplies may increase provider administration costs, and could stifle innovative ideas of getting vaccine to all the children who need it.

Immunizing at every possible opportunity may lead to increased provider education and administration costs and a need to verify existing records to ensure that vaccinations aren't redundant. Financial incentives such as capitation will lead to increased referral away from the private setting, and may lead to a decreased use of immunization resources.

Deleted: ¶  
Subsidize vaccines for children brought to the physician in a private primary care setting (Zimmerman, 1997). ¶  
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Plusses: ¶  
¶  
Decreases the loss of immunization due to inability of the parent/guardian to follow up on referral.¶  
¶  
Minuses: ¶  
¶  
Overlaps with public health clinics currently serving inner-city and other underserved children. ¶

### 3. *Expand educational and media resources regarding the vaccination schedule and the different funding and delivery programs*

Public education including information on all the possible ways to get a child vaccinated could be made widespread. Current education efforts seem to focus more on providing information when a vaccine is administered, to ensure that the patient is aware of the potential adverse effects, how to recognize them and what to do in case they occur. This is very important, but does not directly lead to improved vaccination rates, and much more can be done to increase the public information about which vaccines are required and when (Cookson, 2002).<sup>23</sup>

Both providers and consumers need to be more aware of the vaccination schedule, the different avenues for getting immunized, and how to access them (Lieu et.al., 1994; Hughart et.al., 1997; Clark and Freed, 1998). Education can occur in a variety of settings: all health care clinics and departments, during maternal pre-natal visits (Evers, 2001), during well- or urgent care visits (Taylor et.al., 1997b), during social worker encounters, leaflets, public posters, oral community sessions. Promotional material should be prepared at a level that is easily understood by the target population (Evers, 2001). Spanish radio is apparently a good way to communicate the importance of immunizations to inner-city Latino communities (Wood et.al., 1995).

#### **Plusses:**

Everyone becomes more informed and conscious of what must be done at each point in infant development. Better provider knowledge is likely to have far-reaching effects. Well baby care would be enhanced.

#### **Minuses:**

Increased provider administration costs.

### 4. *Outreach Alternatives*

#### ***Mobile vaccination units.***

The “unit” may be a fully equipped vehicle that is driven around the relevant neighborhoods, or else merely the mechanism for achieving vaccination within the home. Such a unit could be a fully privatized operation, or structured in collaboration with a social work organization. This approach has been shown to represent an alternative method for health care delivery to elderly residents in rural areas (Alexy and Elnitsky, 1998). It may or may not be combined with the training of other personnel, such as social workers, to administer vaccines.

#### **Plusses:**

<sup>23</sup> While public education and media efforts are not market-based solutions, they will enhance the performance of both public and private vaccine delivery approaches.

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Deleted: with appointment reminders.

Deleted: 4. *Require providers to ensure a local supply of necessary vaccines and monitor their stocks closely. Subsidize private provider vaccine purchases.* ¶

¶  
May improve the efficiency of vaccine market. Purchasers could enter into a sales-volume agreement with the vaccine distributor. The two-tier pricing system could be expanded into a three-tier one: the federally-negotiated discounted price, the catalog price, and an intermediate price negotiated by “vaccine-delivery organizations”, which may have more bargaining power than a managed care organization, but less than the federal government.¶

¶  
**Plusses:** ¶

¶  
Providers will always have vaccines on hand when required. Surveys have shown that a physician with a supply of free vaccine may be less likely to refer a child elsewhere for vaccination (Zimmerman et.al 2001). Enhanced well baby care.¶

¶  
**Minuses:** ¶

¶  
Increased provider administration costs. Could stifle innovative ideas of getting vaccine to all the children who need it.¶

¶  
5. *Required vaccination during well-care visits, urgent care visits, ER and other provider contacts i.e. the administration of vaccine during a clinic visit that was not scheduled specifically for immunization.* ¶

¶  
There are quite a few well-care visits and other unscheduled visits during a child’s first 2 years of life.¶

¶  
**Plusses:** ¶

¶  
Vaccine timing may not be perfect, but probably is still within the general time frame that immunizations should occur. Greater provider contacts will ensure higher vaccination rates.¶

¶  
**Minuses:** ¶

¶  
Increased provider education and administration costs. A need to verify existing records to ensure that vaccinations aren’t redundant. If the child is sick with an infection, immunization is not recommended, and may increase the risk of adverse effects. Which vaccines may be administered in the presence of which illnesses is a topic under debate, and more research may be needed before the safety issues of this practice are resolved.¶

Higher rates of immunization; A mobile unit is a way to get vaccine to infants who would never be taken to a clinic. Besides vaccination, it could also provide other needed public health activities, including risk assessment and well-baby care. Funds saved from reduced provider fees could be re-directed into subsidies affecting other parts of the delivery system.

**Minuses:**

Administrative costs. Training of other personnel may be initially costly; other personnel may not be ready to take on responsibility; infants would miss an opportunity for medical evaluation; liability concerns.

5. *Establishing reliable vaccination records and tracking systems*

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An immunization registry is defined as “a computerized database of information in a defined population, which is used to track all immunizations received by each child”. The key attributes of an immunization registry are reviewed by Wood et.al, 1999. It may or may not be set up in collaboration with a national clearinghouse. It is essential for providers to maintain such a registry. It may be used to decrease missed opportunities to immunize a child by enhancing the possibility to determine immunization status (Watson et.al., 1996). It is also necessary for efficient recall-reminder systems, and audit-feedback mechanisms. The high cost and wide-reaching benefits would need to be thoroughly analyzed before implementation.

**Plusses:**

This would increase age-appropriate vaccination, improve the quality of immunization data, eliminate duplicate documentation, reduce time spent acquiring immunization history (Davis, 2000; Feikema et.al., 2000). The gold standard parent-linked, provider validated registry will also greatly enhance the ability to conduct studies of barriers to timely vaccination, interventions to improve coverage, vaccine safety and vaccine efficacy (Rodewald et.al., 1999).

**Minuses:**

Could discourage immunization of undocumented children. Other privacy concerns are also relevant. Entering and maintaining a comprehensive national vaccination registry would be immensely complex and costly. Challenges faced include the accommodation of the right technology; data accuracy and confidentiality issues; attitudes and beliefs of physicians; and the long-term financing of population-based registries (Davis, 2000; Feikema et.al., 2000). They may also be disappointing in practice as they are only as good as the providers make them (Christakis, et.al., 1999).

6. *Stricter enforcement of HEDIS guidelines that HMOs and health plans should cover vaccinations and achieve full vaccination compliance.*

Childhood Immunization Status and Adolescent Immunization Status are both HEDIS® standardized performance measures required as part of the NCQA Accreditation Process for Commercial Health Plans. Although it has been widely embraced by purchasers, consumers and health plans, the NCQA accreditation program is voluntary, and therefore will not ensure universal immunization coverage by health plans (NCQA, 2002). So far, evidence is modest for the success of such policy changes. [A new law that required indemnity insurers to cover childhood immunizations and preventive services in New York State](#) was associated with a substantial decrease in [physician referrals to public clinics for immunization](#) (Szilagyi et.al., 2000c).

**Benchmarking**

[Computerized immunization information may serve to make physicians more accountable through periodic assessment and benchmarking of clinical decision makers and private provider practices](#) (Orenstein and Bernier, 1994). The use of the Standards for Pediatric Immunization Practices (NVAC 1993) creates useful benchmarks.

**Plusses:**

More health insurance plans will provide reimbursement for vaccination at a primary care clinic. Lower quality plans may be “weeded out”. Insurance coverage for low-income families may result in a shift in the provision of immunizations from the health department to primary care providers and in increased immunization coverage (Rodewald et.al., 1997).

**Minuses:**

Enforcement costs. Runs a risk of lowering quality: mandating minimum quality standards without also mandating increases in access to specialty care has been shown to lead HMOs to set quality at the minimum standard, even when their quality would be above the standard in the unregulated market. The current quality floor becomes the future’s quality ceiling in the HMO market (Encinosa, 2001)

*7. Incentives for the use of childhood combination vaccines*

Combination vaccines contain multiple antigens. A review of the relevant pediatric literature ensures that FDA standards are rigorous in requiring their safety and efficacy (Halsey, 2001). General guidance is publicly provided on the use of combination vaccines, their interchangeability, the logistical challenges involved (CDC MMWR May, 1999).

**Plusses:**

Increased use of combination vaccines will increase compliance with the vaccination schedule leading to higher immunization rates, decrease the number of visits to the clinic and administration charges. It is also easier on the child (Freed et.al., 1996; Decker, 2001; Le, 2001; Lieu et.al., 2001).

**Deleted: 9. Establishing reliable vaccination records.** ¶  
 ¶ Keeping an immunization registry with a vaccination record for each child. Could be done with a national clearinghouse tracking children with a vaccination card/record issued at birth.¶  
 ¶  
**Plusses:** ¶  
 ¶ Vaccination records are useful on many levels, from monitoring immunization rates, to helping compliance with a vaccination schedule, to determining which regions have relatively lower vaccination rates.¶  
 ¶  
**Minuses:** ¶  
 ¶ Could discourage immunization of undocumented children. Other privacy concerns are also relevant. Entering and maintaining a comprehensive national vaccination registry would be complex and costly.¶  
**Deleted: 10.**

**Minuses:**

Practical issues that may arise from the use of combination vaccines include the increased necessity for improved vaccination records, and the low likelihood of the administration of consecutive doses of vaccine being from the same manufacturer (Decker, 2001), although the interchangeability of vaccine products ought not to be an impediment to completion of the recommended immunizations (Feldman, 2001). There will be increased uncertainty about adverse reactions and increased complexity of vaccine information. The vaccines will be more expensive. They may also not market well unless they demonstrate both financial savings and convenience for vaccine providers (Le, 2001).

8. Innovative Delivery Systems

8.1 Encourage development of heat-stable vaccine technologies, encourage adoption where the technology is available

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Current storage and handling of vaccines in private provider's offices is less than optimal (Bell, et.al., 2001).

**Plusses:**

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Easier to store and keep a ready supply; being outside the cold chain simplifies the logistics and increases the speed and efficiency of vaccinations in alternative settings.

**Minuses:**

Will probably not be available for a while, and even then, safety and efficacy must be assured.

8.2 Advanced time-release vaccine delivery system injected or implanted at birth, releasing all appropriate childhood vaccine components at the correct times over the first two years of life.

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**Plusses:**

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Eliminates post-birth vaccination visits, reducing time spent in going to clinic. Makes administration and record-keeping much easier. Full compliance with vaccination schedule.

**Minuses:**

Technical barriers are formidable. It will probably be quite a while before this technology is feasible. Safety concerns may be an issue. It may reduce incentives for standard well-baby care.

8.3 GPS Infant Two-way Paging System

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Technology currently exists for a two-way pager that tracks exact location through the GPS satellite system. Underserved infants could be provided with a “wrist-watch” or anklet tracker system that would beep/flash whenever they were supposed to receive vaccines. The parent/guardian would either call the provider to arrange vaccination, or a mobile vaccination unit could track the child directly. The system would only be provided under written informed consent of the parent/guardian. Parents would have an incentive to sign up for the service, since the tracking device would also serve as a lost child locating device and illness monitor. Any missing child could be tracked. Children could be monitored on an emergency basis if their tracker moved outside of a specified area or was removed from the child. The device could also measure vital signs such as body temperature or heart rate and send alerts if these parameters were out of range.

**Plusses:**

Currently technically feasible at relatively low cost, particularly if the parent/guardian is interested in the “child-monitoring” features anyway.

**Minuses:**

Privacy concerns.

**Conclusions**

A number of policies could be implemented to enhance vaccine market performance on both the supply and demand sides. While some policies would be relatively easy to implement, some would require significant changes in law and public finance. Nevertheless, there are substantial opportunities available to ensure that a vigorous private market in vaccine development, manufacture and distribution will continue to make valuable and important contributions to the nation’s health.

*Supply Side*

Vaccines are not as profitable as other pharmaceuticals and private firms do not invest in vaccine R&D and production capacity even at the levels of R&D for other pharmaceuticals.<sup>24</sup> Even if there was parity in investment between vaccines and other pharmaceuticals, because of their public goods characteristics, vaccines would still be under-supplied and vaccine R&D and production capacity would be sub-optimal in a fully private vaccine market. Given the unique characteristics of the vaccine market and vaccine market regulation, some combination of direct expansion of government “push” programs and new types of reward-based “pull” programs would be preferable to the current vaccine market regime.

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<sup>24</sup> Hopefully, the CDC and the vaccine market is not a harbinger of what would happen to other pharmaceuticals if Medicare became a similar monopsony purchaser of pharmaceuticals.

Kremer-type vaccine development rewards programs could substantially enhance the private sector vaccine market over the current patent rewards system by encouraging greater competition and manufacturing capacity among suppliers with market prices close to marginal cost of production for all consumers. In addition to stimulating more vaccine development this would eliminate the complexities of multi-tiered pricing for different payers.

#### *Demand Side*

Consumer and provider education and the efficient use of up-to-date vaccination registries are elements essential to the success of any market-oriented solution. It is inherently difficult to identify the most feasible and cost-effective solution to vaccine delivery for all locations. One size does not fit all. Different approaches may work better in different states or within different localities. It will take a range of efforts directed at both the providers and the consumers to ensure efficient, age-appropriate vaccination of the entire population. The costs and benefits of various approaches should be examined carefully.<sup>25</sup>

The public nature of vaccinations leads to under-provision in a purely private market. However, the offsetting vaccine delivery problem is the moral hazard associated with the implementation of any solution that involves free or subsidized vaccine delivery. Targeting subsidies at underserved populations can create additional incentives for others to take advantage of the system, even if they would have purchased vaccines anyway. The participation of results-oriented competitive private organizations in the vaccine delivery market will enhance vaccine coverage while limiting benefits only to those who need them.

Optimal immunization rates can probably only be achieved through the combination of diverse solutions. Each local community will need to experiment to find the solutions that work best in their own contexts. A competitively bid market for local vaccine administration programs provides a useful platform for this sort of experimentation.

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<sup>25</sup> It should be noted that herd immunity considerations indicate that vaccine coverage rates of 60%-80% may be adequate to prevent disease spread, depending on the disease, the pathogen and host dynamics. These issues need to be considered in determining what vaccine population coverage rates are acceptable (DeJong M, Bouma A 2001).

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