

**HOW INSURANCE COMPANIES AND HEALTH PLANS ARE
PLANNING FOR NEW VACCINES**

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**Background Paper
Prepared for the Committee on the Evaluation of
Vaccine Purchase Financing in the United States**

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500 5th Street, NW
Washington, DC 20001**

January 23, 2003

Prepared for the Institute of Medicine, Committee on Evaluation of Vaccine Purchase Financing in the United States, with the assistance of Jessica Seabury, MS Candidate, Harvard School of Public Health.

How Insurance Companies and Health Plans Are Planning for New Vaccines

For the past 15 years, there has been a tacit expectation among many health policymakers that the financing of childhood immunizations would be a shared responsibility of the private and public sectors. Employers and private health insurance would cover the costs of immunizing children of workers, and the federal and state governments would be responsible for financing the immunizations of low-income uninsured and underinsured children, as well as children covered by Medicaid. Until 15 years ago, the costs of immunizing a child were relatively low. In 1987, the combined catalog price of all childhood vaccines was \$116; ten years later, the total price was between \$332 and \$370 (IOM, *Calling the Shots*, p. 57). Since 1985, the number of recommended childhood vaccines has doubled, helping to drive the total price of the recommended vaccines up.

The rising costs and number of current childhood vaccines have raised concern that the shared private-public responsibility for childhood immunizations may be shifting from a 50-50 split to one where the private sector is reducing its commitment to financing immunizations. This concern has been partly fueled by anecdotal stories related to the recent shortages of vaccine supplies to private and public providers. The anecdotes describe physicians in private practice telling their patients to obtain immunizations at public clinics because the private practice physicians could not obtain supplies of vaccines. Whether these effects are short-lived or not, of greater concern is the fact that states vary in their requirements that private insurance policies cover immunizations. Only 28 states have mandates or laws requiring that health insurance policies sold within their borders cover at least some of the childhood immunizations (American Academy of Pediatrics, January 2003). Among the states with such laws, the laws differ in terms of which vaccines are included in the mandates and whether there are limits on the cost-sharing required of the family for the vaccines. Further, under the Employee Retirement Income and Security Act (ERISA), employer-sponsored health benefits can exclude

immunization coverage if an employer self-funds (self-insures) the coverage rather than purchasing health insurance policies for its employees. Thus, even under current laws, children with private health insurance do not all have their immunizations financed by such policies. Given expectations that the vaccines now in clinical trials or under development will be significantly more costly than current vaccines, the number of children with private insurance but without coverage of immunizations may increase. If this were to happen, it would undo the current implicit private-public sharing of the financing of children's vaccines.

A second factor that will have a bearing on the private-public sharing of the financing of vaccines is that the vaccines currently in clinical trials or showing promise in earlier stages of development are strikingly different from the present set of vaccines for children and adults. They are expected to be expensive relative to the current vaccines, and a large proportion of the new vaccines will be for diseases that do not have a high prevalence in the general population. The vaccines are likely to be for sub-groups in the population that have greater exposure or high risk factors for the diseases. Given the greater degree of specificity of vaccine appropriateness, the new vaccines are more similar to pharmaceuticals than to the older vaccines. As a result, even if private insurers were required to cover the new vaccines or the Advisory Committee on Immunization Practices (ACIP) were to recommend them, many of the children or adults who would be candidates for the vaccines would be low-income and not covered by private insurance. This would further reduce the private sector share of the financing of vaccines for children, and could have a significant impact on the public sector's costs for adult vaccines.

Thus, the private-public sharing of the financing of childhood immunizations seems to be threatened, and the financing of adult vaccines, already problematic, will become an issue if the new vaccines for adults are as expensive as expected. The shift in the sharing of vaccine financing, especially for childhood vaccines, has two implications for policymakers. First, it raises immediate concerns for the stated federal public health goals of immunizing at least 90 percent of all children 19-35 months of age for communicable childhood illnesses (*Healthy People 2000*). Second, it raises the issue of how to either require the private sector to cover

immunizations or raise funds to pay for a greater public role in the financing of vaccines.

This paper provides information about how some private insurance companies and managed care plans (hereafter jointly referred to as “carriers”) are planning for vaccines that are currently under development, both for childhood and adult illnesses. This information should simultaneously ease and heighten concerns about the private-public sectors’ sharing of costs of immunizations, especially childhood immunizations. On the one hand, interviewees at the health plans and insurers that spoke with me say they will follow the recommendations of the Advisory Committee on Immunization Practices (ACIP), just as they have in the past. On the other hand, the new vaccines are generally not for diseases that have either a high prevalence rate in the general population or high mortality rates. Rather, the vaccines prevent diseases that are usually found only in small sub-groups of people, and the medical costs of the illnesses are often low relative to the costs imposed by the illnesses on the person’s or child’s family, in particular a parent’s time absent from work. Thus, it is not clear that the ACIP should recommend that all children or all adults receive the newer vaccines. In the case of childhood illnesses, the children for whom the vaccines may be recommended may be children less likely to have private health insurance because they are poor or in parts of the country with higher uninsured rates. These children will need public sector financing of such new vaccines.

The paper has two parts. First, I provide background on the current private-public financing of vaccines, particularly children’s vaccines. This section briefly describes the gaps in private insurance coverage of immunizations. Then in the second section, I describe the six key themes that emerged from my interviews with 16 people at indemnity insurance companies, managed care plans, and public health departments. The objective of the interviews was to learn how private insurers and health plans are planning for the new vaccines, and what their thoughts were about covering them. Finally, I draw some conclusions and policy implications from the findings from the interviews.

Background on Private and Public Financing of Vaccines

The federal government currently finances childhood vaccines through two programs: Section 317 of the Public Health Service Act and the Vaccines for Children (VFC) program. Section 317 funding is provided to the states for the purchase of vaccines for children who are not eligible for VFC funded vaccines, as well as vaccines for adults. In general, the vaccines purchased through Section 317 funding are provided to public health clinics. Section 317 funding also is used to support states' immunization infrastructure that, in addition to providing immunizations, is responsible for surveillance activities connected to the diseases meant to be prevented by vaccines, outreach and education activities to increase immunization rates, and the development of a national immunization registry. The funding for the Section 317 grants is allocated every year in the federal budget process and flows through the Centers for Disease Control (CDC). States submit applications to the CDC for their annual allocation. However, the funds are not divided among the states according to a formula that takes into account the number of children or the number of adults in different age cohorts who might be expected to be at risk for various diseases. States have generally supplemented their Section 317 grants with state funds to purchase vaccines and support the public health immunization infrastructure.

The VFC program was established in 1993 with the objective of increasing immunization rates among children who are not covered by Medicaid or private health insurance. A major catalyst to the implementation of the VFC program was the 1989-1991 measles epidemic. Analyses of the epidemic concluded that low immunization rates among children younger than 5 years were a major reason for the outbreak. Thus, the goal of the VFC program is to boost immunization rates, particularly among low-income children. Under the VFC program, vaccines are provided by the Centers for Disease Control at no cost to the states for VFC-eligible children – children under the age of 19 who meet at least one of the following criteria: enrolled in Medicaid or are Medicaid-eligible (but not enrolled); uninsured; underinsured and receiving immunizations at a federally qualified health center (because the insurance does not cover immunizations or requires a large copayment by the child's family); or Native American or

Alaskan Native. The VFC vaccines are an entitlement for the eligible children; because the program is an entitlement program, the funding for the vaccines is not subject to the federal budget allocation process. However, the costs of the public health infrastructure for immunizations and the payments to providers for administering the vaccines are paid for by the states. Since a second goal of the VFC program was to get children immunized in their “medical home” (i.e., their pediatrician’s office), the payments to providers for administering the vaccines is a considerable cost to states and providers.

Complicating efforts to boost immunization rates with the VFC program is the fact that if a child enrolls in a State Children’s Health Insurance Program (SCHIP) that is not part of a state’s Medicaid program, a child can become ineligible for VFC vaccines. The reasoning is that once a child has SCHIP coverage, the child is no longer uninsured – and therefore is not VFC-eligible. Further complicating the funding streams for SCHIP children’s immunizations, the CDC and the Centers for Medicare and Medicaid Services (CMS, formerly HCFA) ruled in 1999 that Section 317 funds cannot be used to purchase vaccines for SCHIP children. Clearly, the incentives are for state and federal SCHIP matching funds to be used to pay for the vaccines and the immunizations fees for providers. However, the effect may be lower immunization rates among pre-schoolers and then increased costs to state and local governments that fund public clinics for childhood immunizations when children enroll in school.

Government financing of vaccines for adults is far less generous and consistent than that for children. Section 317 grants can be used by states to provide immunizations (principally for flu and tetanus) to adults in public clinics. Some states, especially those with universal vaccine purchase (UP) programs, provide adult vaccines to public clinics.

Private sector financing of immunizations comes primarily from health insurance, both from indemnity insurers and health plans. There is considerable variation in the extent to which private health insurance covers the costs of immunizations for children and adults. The variation depends on type of insurance, the state where one lives, and whether the health coverage is from an employer that self-funds (self-insures) the plan. Some indemnity insurers offer coverage of

immunizations but unless they sell policies in states that mandate immunization coverage, they do not have to include immunization benefits. Health plans that are federally qualified health maintenance organizations must cover childhood immunizations. Almost all managed care plans cover immunizations that have been recommended by ACIP. Managed care plans generally do not have a separate copayment for immunizations, although the visit in which the immunization is administered may have a copayment (e.g., \$10). Indemnity insurers and preferred provider organizations (PPOs), on the other hand, may require cost-sharing for immunizations if they are a covered benefit. For the indemnity insurance policies especially, the cost-sharing is based on a coinsurance rate, which most often is 20%. The cost of the immunization may be exempt from the deductible for the policy but usually it is not. If the policy is an employer-sponsored policy and the employer is large, the details on the cost-sharing may be an issue that is negotiated between the employer and the insurer.

Further variation in private insurance coverage of immunizations exists because, under ERISA, self-funded plans are exempt from state mandates on benefits, and the plans can set limits on how many dollars worth of a particular benefit is covered. As a result, not everyone who has private coverage and lives in a state with a law requiring coverage of childhood immunizations has such a benefit. In general, self-funded plans that use HMOs as their providers/third-party administrators do cover childhood immunizations. Also, in states with laws requiring at least some childhood immunizations be covered by policies, there is evidence that some self-funded plans cover childhood immunizations (Albert B. Sabin Foundation 1996). But in general, we do not know how many people are in self-funded health benefit plans that do not cover immunizations.

The cost-sharing required by carriers for immunizations, and the extent to which people have health benefits that do not cover immunizations, places different out-of-pocket burdens on people depending on their incomes and where they live. Twenty years ago, when most people with health insurance had indemnity policies that did not cover immunizations, the costs of childhood immunizations were not viewed as high. With the increases in vaccine costs and

number of recommended vaccines for children, the burden of the out-of-pocket costs has become more problematic in recent years. This has particular relevance when thinking about possible changes in health insurance benefits packages in the future. Meyer and Waldman (2000) have pointed out the potential problems for immunization coverage if there is a large-scale shift of employers to “defined contribution” health plans from the current “defined benefits” health plans. Under defined contribution plans that have been proposed, employers would sponsor catastrophic indemnity insurance plans and contribute a defined amount to a tax-sheltered, health reimbursement arrangement (HRA) for each employee. The employee could then use the money in the HRA for medical expenses below the deductible, which would be greater than the employer’s contribution to the HRA. This shifts more costs to people covered by such health plans (Swartz 2001/2002; 2002). If people expect to have medical costs that are greater than the defined contribution they receive from an employer, so they have to pay the full costs of immunizations, they may delay or forego immunizations. This is particularly likely if they have qualms about immunizations’ side-effects.

The combination of the burden of out-of-pocket expenditures for immunizations (especially childhood immunizations) and the public health goal of raising immunization rates among children 19-35 months of age to at least 90 percent (*Healthy People 2000*), caused many states in the last two decades to mandate immunization coverage as a benefit of health insurance policies sold within their borders. As noted above, only 28 states have laws or regulations requiring that carriers cover at least some childhood immunizations (AAP, January 2003). However, the laws and regulations vary considerably in terms of which immunizations are included and the cost-sharing required of policyholders. Some states’ laws are worded such that all immunizations recommended by ACIP or the American Academy of Pediatrics (AAP) must be covered; others say that those immunizations recommended by ACIP or AAP as of the date when the law goes into effect must be covered; some name specific immunizations so that any not on the list are not included in the mandate. Half of the states require that there be minimal cost-sharing on the part of the enrollees (that is, that there be first-dollar coverage of the

immunizations so they are exempt from any deductibles and copayments). Only 11 states have regulations related to adult immunizations, and many of those are simply for the safety and health of health care workers (that is, they are a requirement for employment) or adults living in group living arrangements.¹

Interestingly, the two biggest boosts to private sector coverage of childhood immunizations have been the Health Plan Employer Data and Information Set (HEDIS) and state or county laws requiring immunizations for school entry. The National Committee for Quality Assurance (NCQA) has been measuring health plan performance with the HEDIS, which includes immunization coverage rates among children as one of its chief measures. Many employers now use HEDIS to evaluate private insurance plans when choosing plans to offer to employees. All states now require proof of immunizations being up to date for school enrollment, and many have similar requirements for enrollment of pre-schoolers in licensed child-care facilities and nursery schools. Concerns have been raised recently that the school enrollment requirements are causing children with private insurance to obtain the more expensive vaccines from publicly funded immunization clinics that have been set up at the schools (Freed et al. 2000).

Thus, over the last decade, the public-private mix of financing for childhood immunizations has been increasingly shifting towards public funding. How far this shift has gone is not clear. However, it raises concerns about the private sector's financing of vaccines that are currently being developed, both for childhood and adult illnesses.

¹ More precisely, 11 states have regulations that recommend some level of adult immunization coverage by private health plans. In addition, some states have regulations related to immunizations and/or testing for diseases for certain types of workers and residents of group housing. Seventeen states recommend influenza and/or pneumococcal immunizations for residents and/or employees of long-term care facilities. Medicaid pays for immunizations for beneficiaries who are residents of long-term care facilities. Four states have regulations that recommend immunizations for health care workers who perform exposure-prone procedures. Thirteen states have laws that recommend that emergency medical and law enforcement personnel receive testing and vaccinations for certain diseases, most commonly hepatitis B and hepatitis C. Note that the regulations recommending immunizations and testing for certain types of workers do not require that the insurance companies of the workers finance the vaccines and testing – the regulations leave it to the employer and employees as to how the services will be financed.

Private Sector Planning for Coverage of Future Vaccines

In order to understand how indemnity insurance companies and managed care plans are planning to deal with vaccines expected to win FDA approval in the next few years, information from a variety of indemnity insurers and health plans as well as state public health departments was gathered in semi-structured interviews. The interviews were done by telephone between July and October 2002; each interview generally lasted about 15 to 20 minutes. The people who were contacted were most often physicians who are medical directors and/or members of Pharmacy and Therapeutic Committees (“P and T” Committees) of the insurers or plans. Several people were also in top-level management positions. The 17 people who were interviewed are not a statistically representative sample of people in all the indemnity insurers and health plans who are responsible for decisions regarding immunization policy, and therefore the information summarized below may not be representative of such decision-makers.² The people interviewed are in quite different types of plans and are located in the northeast, upper midwest, and California. In spite of their differences, the themes that came out of the interviews were remarkably consistent.

The interviewees who are employed by carriers were asked if they expected the carriers they work for to cover vaccines that are likely to be approved by the Food and Drug Administration within the next few years, and how they make decisions about covering vaccines. They were also asked how the recent shortages of vaccines, state budget shortfalls related to state financing of vaccines, and concerns about bioterrorist threats had affected the ability of the

² The people interviewed were promised anonymity so I will not identify them by name or organization. They were from two states’ public health departments, eight different health plans, two indemnity insurers, and two people who are academics or consultants to states or health insurers about vaccines. Altogether, I spoke with three people in state health departments, 12 people in health plans and indemnity insurance companies, and two academics/consultants. I contacted other people as well but interestingly, several told me to speak with some of the people I already had interviewed because they viewed these people as most knowledgeable about how carriers around the country are planning in anticipation of future vaccines or how they are reacting to new vaccines.

insurers and health plans to focus on vaccines currently in trials. The five interviewees who work for public health departments or who consult with carriers were asked for their perspectives on these issues, particularly in terms of how they interacted with the carriers in providing information.

Six major themes emerge from the discussions in the interviews:

1) *It is not correct to assume that carriers in the states with regulations or requirements regarding childhood or adult vaccines will automatically cover the new vaccines.* Two reasons stand out. As noted earlier, states differ markedly in what their regulations or mandates actually say, and in their requirements for first-dollar coverage of immunizations. Thus, in states that do not specially say that all immunizations recommended by the ACIP or AAP must be covered, it is likely that new vaccines that are not so recommended will not be covered. Second, many of the new vaccines likely to gain FDA approval in the next few years are expected to be significantly more expensive than current vaccines and are likely to be recommended only for children or adults with specific contributing risk factors. Between the expense and the restricted appropriateness of the new vaccines, it is unlikely that state health departments or legislatures will require that all children or adults receive the new vaccines.

2) *It is difficult for carriers to plan for vaccines still under development.* The prices of the vaccines under development are very difficult to forecast, and recent experiences with several childhood vaccines (for example, pneumococcal conjugate) caused many health plans to significantly under-estimate the prices. When the insurers and health plans under-estimate prices, it has real repercussions on the companies' financial bottom-line. Almost all carriers set their premiums for the contract year at least 5 months before the contract year begins. If a vaccine is recommended after the premiums have been set, the carrier is caught short in terms of revenues covering the expense of the vaccine and its administration. In the case of the pneumococcal conjugate vaccine, the price was set at \$60 per dose after ACIP recommended it – much higher than what most plans had estimated. Children were supposed to receive 4 doses, so if a plan had 250,000 children for whom the vaccine was recommended, that cost would be \$60

million – most of which the plans had not included in their premium calculation.

The people who were interviewed said that although they track vaccine development as best they can, they are constantly caught between the pressures of trying to be competitive with the lowest premium possible and wanting to protect themselves from a vaccine recommendation by ACIP that will increase their costs. The result, as one person said to me, is that the carriers are becoming “skittish” about planning for new vaccines, and they are re-evaluating the basic precepts for covering vaccines. One medical director also told me in this context that he/she feels that people think they cannot become sick with many of these illnesses since the diseases are rare now in the US – and then question why they should pay for the vaccines. The medical director worries that this may lead the U.S. to become more like other countries that seem to tolerate higher rates of childhood (or adult) illnesses among the population.

The new combination vaccines also are a worry to the people I spoke with. Ultimately, some may not be licensed by the FDA, making planning for them an issue, but the over-riding concern is how they will be priced. The consensus seems to be that if the pricing is consistent with the prices of the component vaccines then the carriers will prefer them but if the pricing is substantially higher, they will not shift to using them even though compliance and overall immunization rates may be higher with fewer shots.

The lack of pricing information for new vaccines before ACIP makes its recommendations about the vaccines appears to be a major problem for carriers. More than one person told me that ACIP should know the price when it makes its decision about whether to recommend a new vaccine. The current situation, according to these interviewees, is tantamount to giving the manufacturer the right to charge an even higher price if ACIP recommends the vaccine should be given to children.

3) *ACIP's role in whether or not new vaccines are recommended is pivotal to carriers' decisions about when to cover vaccines.* In addition to the concerns above about ACIP's decisions' effects on vaccine prices, the recommendation itself by ACIP plays a pivotal role in the timing of carriers' decisions about covering vaccines. Over the past two decades, there has

been an increased willingness of people to sue vaccine manufacturers and the physicians who administered the vaccines over real or presumed side-effects. The result is that carriers are concerned about their own liability if they should decide to cover vaccines before ACIP recommends that the vaccines be given. As a practical consequence, carriers will no longer cover vaccines before they have been recommended by ACIP.

4) *Carriers differ in how they are able to monitor developments with vaccines that are being developed or are in clinical trials.* Larger and better financed health plans and insurance companies have “P and T” committees with dedicated staff and/or physicians whose responsibility is to read the literature on vaccines in trial or under development. The staff and physicians keep up with the cost-effectiveness literature and reports on the prevalence of various diseases so they can make judgements about the efficacy and cost-effectiveness of the vaccines. They also follow what is happening at the FDA in terms of the approval process for vaccines in clinical trials so they can plan for when the vaccines may be licensed by the FDA. All of these efforts are conducted more to be able to incorporate the prices of recommended new vaccines in the carriers’ premium structure than to arrive at independent judgments about whether the vaccine should be covered.

All managed care plans, especially those that are smaller or with more constrained financial resources, rely on the American Association of Health Plans (AAHP) for advice about vaccines that in development or clinical trial stages. The AAHP is the nation's principal association of health plans, representing more than 1,000 plans that provide coverage for approximately 170 million Americans nationwide. Member plans include health maintenance organizations (HMOs) and preferred provider organizations (PPOs). AAHP provides a wide range of services to its members; one of which is information on new pharmaceuticals and vaccines. Thus, if a health plan cannot afford to devote its own resources to following the developments of new vaccines, it can obtain quite comprehensive information from AAHP.

5) *Planning for new vaccines has been somewhat interrupted during the past year by concerns related to bioterrorist threats.* Over the past 15 months, the CDC and the Office of

Homeland Security (now the Department of Homeland Security) have been issuing a large number of warnings and information bulletins about threats related to anthrax and smallpox, as well as other biological agents. The result has been that many carriers' decision-makers responsible for following developments related to new vaccines are often overwhelmed. They have had little time in the past year for focusing on new vaccines in clinical trials. In addition, state shortfalls in revenues are affecting the purchasing of vaccines (especially in universal purchase states) and paying for the administration of vaccines. These problems impact the carriers to the extent that the supplies of vaccines also affect their immunization rates. These difficulties have distracted public and private sector decision-makers in their ability to plan for new vaccines.

6) *Decisions about coverage of new vaccines may hinge more on “real politik” than cost-effectiveness analyses.* For example, I asked several people about how they are planning for or think other carriers are planning for the HPV vaccine that is expected to be available in about 5 years. Their response was that they expect to cover it (although this was usually hedged by “depending on the price”) but not because it might save the carrier money. Rather, the decision rationale would be that it would be difficult not to cover the vaccine – women are perceived to make the decisions in a family about which plan to join, and women generally dislike PAP tests and are scared of cervical cancer.

Some people also told me that they are very concerned that the new vaccines will not be appropriate for everyone in the general population and that it will be important for ACIP to make distinctions as to risk factors that might help identify who would benefit from the vaccines. Some the vaccines in development, for example, are for diseases that are not prevalent in the general population but have high prevalence rates among some sub-groups of the population. Examples of such diseases are Hepatitis A and diseases frequently found in less-developed parts of the world. In urban areas with large numbers of immigrant groups who travel back and forth to countries they emigrated from, the prevalence of such diseases is sufficient to consider vaccines appropriate. Likewise, Lyme disease is an example of a disease for which a vaccine

was developed but many people in the U.S. were not at risk for Lyme disease and it would be inappropriate to recommend that everyone be vaccinated against it.

Similarly, there are vaccines that may be appropriate only for very young infants or for adults with specific risk factors. Many of the vaccines under development for adults are specifically for people who have diseases (for example, melanoma or metastatic cancers). Several interviewees pointed out, however, that there likely will be large “gray” areas of who is appropriate for the vaccines. This creates potential budget problems for the carriers, especially if there are mandates about particular vaccines. The problem for carriers then will be to create “hard lines” with providers so the providers do not give the vaccines to people who really are not appropriate candidates. An example of this that was mentioned is a treatment that has been developed for RSV (respiratory syncytial virus) in premature newborns. RSV causes a bad cold and cough with bad wheezing, which can lead to hospitalizations for newborns, particularly those who are born prematurely within a few months of the winter flu season. A new treatment involves single-cloned gammaglobulin, at \$1,000 per shot and shots have to be given monthly during the winter months. Thus, the total treatment cost is about \$7,000 per baby. The manufacturer of the treatment is marketing it as a treatment for all babies, but the costs prohibit such a move. The dilemma for the carriers is to set rules that will reduce the “gray” area of which infants are appropriate candidates for the treatment.

If mandates are passed requiring general coverage for new vaccines, carriers may be forced to provide the vaccines to many people for whom it is not appropriate – and the costs for this may be significant. The financial costs will raise premiums, and many people will have side-effects to which they did not need to be subjected. Most of the interviewees expressed concerns about being required to provide vaccines to the general population when the vaccines are appropriate only for sub-groups. The carriers would prefer flexibility and provider discretion such as they have with prescription drugs for treating illnesses.

Based on these six themes that emerged from the non-random interviews, it appears that carriers are having a difficult time planning for vaccines that may be available in the next 3 to 5

years. The carriers' planning for future vaccines is driven by a need to time coverage of vaccines in an exquisitely narrow time-frame. They need to avoid being caught short by the costs of ACIP recommended vaccines and yet they do not want to cover the vaccines before ACIP recommends that they be provided. In addition, the relevant people at the carriers are sometimes swamped by having to respond to the shortages of vaccines, trying to catch up with children who are no longer on schedule for their immunizations because of the earlier shortages, and responding to homeland security bulletins and warnings about smallpox and anthrax as well as efforts to rebuild public health infrastructure in their locales. They were all worried about the potential for rising disease rates as a result of the vaccine shortages and what they view as the competitive reality in the insurance marketplace that causes people to resist paying for the immunizations. Several people spoke about the need for community discussions and community decisions about the costs and benefits of the newer vaccines.

Conclusions and Policy Implications

It is not realistic to look to private insurers to take the lead in decisions about coverage of vaccines that will be licensed in the next few years. It is difficult for insurers and managed care plans to plan for coverage of vaccines still in the development and clinical trial stages. The prices at which vaccines will be sold are very hard to predict. Forecasting when, if at all, the FDA will license a vaccine, and whether or not the ACIP will recommend that a licensed vaccine be provided, are plagued by uncertainties. In addition, there is some uncertainty about whether the FDA or ACIP will reverse decisions about vaccines. During the past decade, such decision reversals have caused the public to question public health advice about vaccines, and to be more willing to bring law suits against providers for possible side-effects. Carriers do not wish to make vaccine coverage decisions ahead of the ACIP lest they be held liable for potential side-effects.

Many carriers also are dubious about the appropriateness of new vaccines for the people enrolled in their plans. As a result, they are cautious of the idea that they should be required to

cover the new vaccines as if they should be administered to all people. Many of the vaccines currently under development are for diseases that differ in two significant ways from the diseases the current armament of vaccines prevent. The new vaccines are expected to be for diseases that are not prevalent in the general population and for diseases that may have greater societal costs than direct medical costs associated with morbidity. The shift to creating vaccines for diseases that have high prevalence only in some sub-groups of the population means that carriers that have policyholders in these groups will have higher costs and premiums than other carriers. This may cause some carriers to deny coverage to people in such sub-groups.

Equally important, preventing the spreading of such diseases to the broader population is a public good – and it can be asked why such vaccines are not publicly financed. Similarly, vaccines are providing benefits to many stakeholders when they are for diseases that have high social costs (for example, children with viruses that cause diarrhea keep parents home from work) but small direct medical costs. Again, it might be asked if such vaccines should be publicly financed since the benefits are recouped by the community at large rather than the carriers.

Overlaying carriers' concerns with the uncertainties about pricing and timing of new vaccines have been distractions connected to bioterrorist threats so that decision makers in carriers have been less likely to think about vaccines that might be approved several years from now. For carriers in major metropolitan areas, the bioterrorist threats have been a major distraction, while for other carriers they were not a significant problem.

Finally, shortages of various childhood illness vaccines and flu vaccines in the last couple of years have contributed to lapses in compliance with state mandates or requirements that carriers cover childhood immunizations. It is not clear what the long-term effect of such compliance lapses will be. But people in public health departments and carriers were concerned that the shortages have not only contributed to a fall-off in immunization rates for some age cohorts of children but also caused an increased demand for immunizations provided by publicly funded clinics when the clinics are perceived to have supplies of vaccines. Especially when

providers have difficulties obtaining supplies of vaccines, people may be more likely to seek immunizations at public clinics even though their health policies cover immunizations. Public health departments have been frustrated by the supply shortages that have caused this shift in the provision of immunizations. Their primary concern is restoring the immunization rates to what they were 5-6 years ago and preventing outbreaks of preventable illnesses.

The new vaccines pose challenges for health policymakers in both the private and public sectors. The significantly higher prices that are expected for the new vaccines as well as their targeted nature for specific diseases or people with specific risk factors make planning for coverage of them difficult. In the case of childhood vaccines, the status quo of the public and private sectors each being responsible for financing half the immunizations seems to be endangered by many of the new vaccines in development. To the extent that many of the new vaccines will have high societal benefits, weight should be given to the argument that the vaccines will be public goods and should therefore be publicly financed. In addition, the new vaccines often seem more like prescription drugs in terms of both their appropriateness for targeted sub-groups within the population and preventing serious morbidity rather than death. This similarity would argue for caution on the part of requiring indemnity insurers or managed care plans to treat the new vaccines like the current list of childhood vaccines. Instead, the better analogy might be the formulary lists that carriers use for pharmaceuticals. In sum, the new vaccines under development are going to break new ground in how we finance vaccines.

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