7 Liability

On June 25, Leslie Cheek, chief of the Washington branch office of the American Insurance Association, made a courtesy call to Meriwether, Meyer and Sencer, among others, on a conference hook-up. He told them what he'd spent a week determining in calls around the casualty industry, which AIA represented. The manufacturers of swine vaccine would not get liability insurance. Liability potential was enormous and worse, uncertain. The necessary underwriting could not be arranged. Existing coverage would terminate June 30, for all manufacturers. Meyer was incredulous. Sencer laughed wryly. Meriwether's reaction is not recorded.

For at least a month, they and their HEW colleagues had known they were in trouble. On May 24, counsel for Merrell, one of the manufacturers, had broken off six weeks of contract negotiations, insisting on indemnification by the goverment for most prospective legal costs associated with the swine flu program. Reluctantly HEW counsel had drafted and the OMB, still more reluctantly, had approved an indemnification bill. On June 15 the Chairman of Parke-Davis, another manufacturer, had wired all and sundry that it stood to lose insurance coverage June 30. This at once became public, which did nothing to enhance the reputation of swine flu vaccine.

The bill had gone to Congress June 16. Its reception had been cool. Neither on the Hill nor in the Public Health Service had threatened loss of coverage been taken literally. Nothing like that had ever occurred with immunization programs.

So June 25 was a shock. Suddenly, the immunization program—just reaffirmed at Bethesda—seemed wholly dependent on congressional action in a complicated field, not previously explored, six weeks before the scheduled recess for Ford's still uncertain nomination. Following Merrell's lead, all manufacturers made plain that they would not insure themselves, not even temporarily. Instead they put off plans to bottle their vaccine; pending legislation they would keep the stuff in bulk. Each week's delay in moving from bulk to bottles assured at least as much delay in starting inoculations. Thus ended hopes of immunizing *any*body in July or even August.

The question becomes, why did the Government run on to June without facing this eventuality? The question is important. The answer takes us back to liability as seen in PHS before Fort Dix. And then we must retrace some steps from January to June.

Liability for vaccine-related injury had been a tender topic with the drug manufacturers since the early 1960's, when the courts had first begun to hand down adverse judgments. The cases were still rare then, most stemming from polio immunization, but the awards were large and the trend unsettling. In 1974 the problem ballooned in the case of *Reyes v. Wyeth* (498 F2nd 1264). Wyeth was another vaccine manufacturer. The circuit court upheld a jury award of $200,000 to an eight-month-old infant who had contracted polio after receiving Sabin live-virus vaccine. The Supreme Court refused to hear the case; the award held. Wyeth had failed to extend an adequate warning of the risk of harm to the unlucky vaccinee. Never mind that the company had included in cartons for shipment a printed form which *did* contain adequate warning. Never mind that experts had testified at trial that this particular case was not vaccine-related. Wyeth would pay (and did). The suffering was real and Wyeth had the ony deep pocket available.

To BoB and CDC, concerned for an assured vaccine supply, the inference drawn from *Reyes* had been that if the government proposed to sponsor mass immunizations, but not to make vaccine itself, it must take over the duty to warn, opening *its* pocket, or indemnify the private firms, or compensate victims directly. The manufacturers were eager to unload the *Reyes* duty. In their eyes it was a quite unreasonable cost of doing business. In the eyes of Sencer's staffers, also many of Meyer's and Seal's, it was a cost of doing business that the manufacturers could all too easily avoid by dropping vaccines from their product lines. So at these staff levels there was a coincidence of interest with the private firms, premised on need for relief from the duty to warn.

At various times staff papers on the subject went to Cooper with no result. In January 1976, just before Fort Dix, the most elaborate of these was sent forward by Sencer as a draft proposal from Cooper to Mathews. Prepared by Sencer's Assistant Director for Programs, Bruce Dull, it urged Federal indemnification wherever there was Federal sponsorship for immunization. The cover memo argued:

> Manufacturer liability for vaccine-associated disability . . . threatens a predictable vaccine supply. . . .
>
> A decision on the Secretary's part to pursue legislation for public management of vaccine-associated disability would relieve the apprehension and anxiety of public health and medical professionals and of biologics producers.

This memorandum may not have reached Cooper, much less Mathews, for it ran afoul of adverse views in Cooper's staff. The issue had been up before, positions had hardened. As an opponent recalled for our benefit:

> Behind these arguments for indemnification there were a number of assumptions which were untested and unsupported by facts. For one, it was contended that if the manufacturers were not indemnified, they would all stop making vaccine. But the number of companies in this business had been diminishing for a long time, for reasons totally unrelated to liability.
> We just couldn't buy this—that continued liability would drive them out.
> And there were other unsupported assumptions, just sort of out there, loping across the plains.

But more than a distaste for coddling manufacturers was working at the top of PHS. There also was concern about ramifications far beyond the immunization field. Indemnification for companies (or even compensation to victims) here could be a precedent almost across the board of public health programs. These were the cautious views of Donald Carmody, an office director on Cooper's staff, professionally a lawyer, who played in-house skeptic about liability proposals. A year before Dull's memorandum, BoB had sent up somewhat comparable proposals. One of Meyer's aides had noted then:

> Any provision for a Federal fund to provide such compensation will meet with objections from H, whether it be through amendment of the Federal Tort Claims Act, or, as CDC is attempting, through amendment of the PHS Act.

Carmody himself told us he thought the "H" meant him.

Beyond issues of substance and precedent were strong instincts on Cooper's part for steering clear of questions where doctors were at the mercy of lawyers. One of his close associates remarked to us:

> As for lawyers, doctors think lawyers are a pain in the ass. Cooper's mind set was to keep lawyers out if you don't want it screwed up.

All this was before the swine flu program. When the manufacturers were asked to make 200 million doses by the Federal government, for Federal purchase, distributed with Federal help, for use at Federal urging in a national campaign, then Federal assumption of the duty to warn became a price one had to be prepared to pay, even in Cooper's view. Assumption of the duty did not seem to him synonymous with reimbursement for all legal costs, to say nothing of compensation for all victims. Rather, it seemed a separable and more modest concession.

Neither Cooper nor Sencer made much of this with Mathews or with

Ford, nor did they try to calculate the program's added cost if *Reyes* awards resulted. They seemed to have expected that the duty to warn, once they assumed it, would be discharged too well for penalties. CDC could draw a good consent form and the vaccine, after all, was safe. As for defending against baseless suits, attorneys would be charged to other budgets than their own, in other fiscal years, no problem for the swine flu supplemental.

Preparing to brief Ford, March 22, Dickson, on Cooper's behalf, had talked at Mathews' staff meeting with St. John Barrett, HEW's Deputy General Counsel. Barrett was acting for Taft, the new General Counsel not yet confirmed. Barrett had a word with Bernard Feiner, the career head of his Business and Administrative Law Division. Meanwhile Cavanaugh, on his own motion, called Attorney General Levi who referred him to Neil Peterson, head of Tort Claims at Justice. Peterson, Feiner and Barrett all reacted alike; the duty to warn could be carried in the government's procurement contract. This was what Cooper and Cavanaugh wanted to hear. It spared them going, hat in hand, to the Rogers and Kennedy subcommittees for substantive legislation, which might slow appropriations and delay the program's start. Comparatively speaking it was better to go to the lawyers. Cooper did so. Mathews approved. Cavanaugh did not demur. The problem did not figure in the issues put to Ford, and landed in the lap of OGC.

No part of HEW was less prepared to cope with liability than was the General Counsel's Office. In form it has a vast array of lawyers, in fact a handful who are not absorbed by endless streams of regulation-writing, bill drafting, contracting or litigating. The number of able attorneys free to tackle tedious and complicated issues without deadlines, lacking pressure from the Secretary, or equivalent, was virtually nil in Barrett's time—and is so still. Nobody had fastened on a problem which a Dull could not get past a Carmody.

Now, however, with a novel form of contract to contrive, Barrett had to improvise. He turned to Feiner because contracts were familiar in the Business Division's work. And Feiner took the task upon himself because, as one of his superiors told us: "He was a good lawyer, meticulous . . . and the only one in the division competent to do it."

Thus Dull's interest in duty to warn survived his paper and was carried by swine flu momentum to the HEW lawyers. But it was stripped of Dull's original concern about production. After all, the manufacturers could scarcely stop producing in the middle of a national program. Swine flu momentum would carry them, too, along with the issue and even despite it.

That is how Cavanaugh, Cooper and Mathews seem to have reasoned and how Barrett and Feiner proceeded, from March through May.

Unfortunately, assuming the duty to warn through contract provisions failed to satisfy the manufacturers. The government could undertake to warn. But suppose the manufacturers should be sued anyway. Suppose the courts should sympathize, enlarging *Reyes*. Awards aside, what of the legal costs to cope with baseless suits? While legal overhead would pass to casualty insurers above a self-insurance limit, might there not be more than enough suits to crowd that limit? Manufacturers accepted their responsibility for simple negligence, but these questions ranged far beyond negligence to an uncharted realm suggested by absolute liability, 200 million doses, friendly juries, and the itch to sue. Yet contract language could not assure indemnity for anything. The Anti-Deficiency Act stood in the way. It barred agency spending without statutory sanction. The courts long since had said this meant no open-ended promises by such as HEW.

Barrett and Feiner, with help from Justice, sought contract language that would stretch the limits of that Act. Washington counsel for three of the four manufacturers joined in with dubiety. As one of them put it to us:

> We would open every meeting with a heartfelt refrain for the HEW lawyers: "We need legislative relief. Nothing short of that is going to do it. [Chairman] Rogers would be willing to put in a bill. We need legislative relief." That was our first paragraph at every session. It fell on absolutely deaf ears. We would watch it fall, and then we would proceed to talk about what they wanted to talk about.

What counsel stressed in their opening comments did not seem to be what their clients were stressing in public statements to others. The clients spoke mainly of duty to warn. Joseph Stetler, President of the Pharmaceutical Manufacturers Association in Washington had twice testified on the Hill; when it came to liability, he asked for indemnification, but he emphasized shifting the duty imposed by *Reyes*:

> . . . Wyeth was sued, held responsible, and told they had the responsibility to advise every person being immunized of potential harm and danger from the vaccine. This is an absolutely impossible requirement, particularly if you are talking about a nationwide immunization program. It is that kind of precedent that makes us very properly concerned about our potential liability under this program. It is a responsibility that is going to have to be shared by the Government in this unusual partnership arrangement we find ourselves in.

By mid-May, Feiner's work on contract language had brought all concerned as far as there seemed any point in going. It may be that the counsel for the three firms would have urged agreement on their clients, trusting to the good will of the government if catastrophic costs were actually incurred. Barrett and Feiner were hopeful then; our interviews suggest they had some reason.

But on May 24, counsel for the fourth firm, Merrell, called a halt. William Rogers, the former Secretary of State, flew in from Cincinnati to pronounce the word. Merrell would not proceed without assurance of indemnification, except for negligence.

Barrett went to Cooper with a question: Did the program really need Merrell's production? Cooper consulted Sencer and then took the answer to Mathews. On their March assumptions it had to be yes. Nothing had changed those assumptions. Merrell was the smallest of the firms but had been scheduled for a quarter of the swine flu production. Reluctantly they acquiesced, as Cavanaugh and O'Neill did in turn, to what the firms and CDC had wanted from the start, an indemnification bill.

Behind Merrell's firmness, there almost certainly was fear of the intentions of the casualty insurers. In May it was no secret that at least some major firms wanted to steer clear of swine vaccine. As early as April 8, Merck had been warned by its primary insurer that coverage for swine vaccine was "considered" not "feasible . . . at virtually any price." So Merck's President had written Mathews and everyone else in sight.[12] Merrell, then about to switch insurers (for unrelated reasons) is reported to have been told by its new one something of the same sort at about the same time. We do not know precisely what was made of this, where, in Merrell's management. We do know that the issue was reviewed again, in June, by the insurer with the same result, a "no." But we assume that Merrell's counsel knew in May what the insurer had already warned in April. However that may be, it shortly would turn out that all insurers saw the swine flu program much alike: *not* for them.

Insurance managements apparently were concerned less with duty to warn and court awards than with that other spectre, overhead costs. Their eyes were fixed on claims and beyond these on law suits. Under prevailing contracts with drug companies, the primary insurers were obliged to defend them in court. Granting the potential for some catastrophic losses, in between awards were all the suits to be dismissed. How many cases, how many lawyers, how much time, what cost? 200 million doses meant how many million claims to overstrain adjusters? Poorly adjusted claims would turn into how many million lawsuits? Suits are fueled by anger. Governmental urging meant how many angry citizens? Would presidential sponsorship, hence "politics" in an election year, anger them still more? This we are told weighed heavily. And back of anger what might be the side effects to give it verisimilitude and lengthen legal process?

These questions defied actuaries. There was no experience. Polio immunization had entailed far fewer numbers with sponsorship free from political taint, in a relatively unlitigious era. The upshot was too much uncertainty for managements like these to bear. They were just coming out of a two-year financial squeeze. They were in business to spread risk, not take it. What they couldn't calculate could not be spread on any terms they cared for. Nor could the primary insurers unload costs of their adjusters and house counsel.

For the insurers, Ford's announcement raised a red flag. Cheek, a Washington lawyer, not previously much exposed to the internal management concerns of those he represented there, has speculated to us:

> I wouldn't be surprised if some president or senior vice-president in each company hadn't happened to catch Ford on the evening news and said to himself: "Every man, woman, and child! I wonder if we cover any of the vaccine manufacturers—if we do, we certainly ought to cancel."

The President of one of the companies smiles at this. He told us:

> It may be so for the others, but in our case it was some junior underwriters who noticed first. Their worry was 'how would a catastrophic award look on my record?' The thing worked its way up. . . . The higher it got the more it was seen in the broader management context, claims and suits: incalculable amounts of overhead cost for which we had unlimited liability. Our Vice President . . . decided not to insure. Then he put his decision to me, which he usually wouldn't do, because of the White House announcement, the public affairs aspect. I simply confirmed his decision. . . . If the public was really endangered, the government should take the risk; it certainly could, we couldn't.

Whichever way decision-making moved, top-down or bottom-up, Cheek would not have known it then. He ran but a branch office for his trade association, watching Congress and explaining why his clients couldn't cover natural disasters. The casualty insurance industry was regulated by the states. It had no Federal agency with which it dealt from day to day, least of all HEW.

Some firms that sold casualty insurance also sold health insurance, but the work was compartmentalized internally, and governmental contracts were facilitated through separate trade associations. The AIA, Cheek's outfit, had its headquarters in New York with many branches of which his was only one. But as he saw it from afar, to quote our interview again:

> If top management asked about particular coverage, it would take

about two weeks for the inquiry to get down to the underwriters concerned and come back up. There would be nothing much else for the top to do except in due course to pass the word back, "When the contracts re-open, don't renew."

If decisions flowed the other way the timing might be shorter.

On April 12, Cheek's boss T. Lawrence Jones came down from New York for a meeting with Lynn on another subject. At the end they had some words on swine flu liability. At AIA it is considered that Lynn then got a forewarning of the uninsurability of swine vaccine. If so, it did not register sufficiently to be passed on. OMB staff do not recall it. Neither does O'Neill or Cavanaugh. And nobody from AIA called Cooper or Barrett.

No aspect of the swine flu case holds more intrinsic interest than the solid wall between decision processes at HEW, on the one hand, and the insurance managements on the other. The drug company managements were somewhere in the middle. How much they knew by when about their prospects for insurance is unclear to us. The chain is long. At one end were the Washington and Cincinnati counsel negotiating with Barrett, next were house counsel and top management of manufacturing subsidiaries, next their counterparts at corporate headquarters, then (in three cases out of four) headquarters specialists in insurance placement, then the outside brokers with whom they dealt, and finally the insurance underwriters heading up to their own managements. And it was not one chain but five, in parallel, from four drug companies to five primary insurers (one of the drug companies was shifting its insurance). Who knew what, when, along these chains, to say nothing of across them, we can only conjecture.

Two things, however, strike us now. First, nobody had incentives to assume the worst except those farthest away from HEW, the insurance managements. Everybody else had incentives to hope for the best. Second, at no time before June did HEW attempt to find or deal directly with its opposite numbers, the insurance managements. Who was to do that? Why? HEW dealt with the manufacturers. As Mathews later told the press:

> The insurance companies are parties to the manufacturers, not to us. We are not in direct negotiations with them except through the manufacturers. . . .
>
> The issue is between them and their manufacturers . . . not between them and us. . . .[18]

Cooper now considers this a lesson to be learned; he told us:

> If I had it to do over again, I would have talked to the insurance

industry directly and not through the drug manufacturers, and I wouldn't have waited too long to start doing it. That's an important lesson.

And Mathews has a retrospective warning for us:

> Mass immunization was like sending the big trucks over an old bridge; the supporting structure was not strong enough to hold up. The liability issue, and behind that, the growing litigiousness of the times, were simply too much.

By that light Cooper's lesson should be underlined. Whenever an unprecedented venture is in prospect HEW officials ought to ask themselves, "What private decision-makers (or public, for that matter) about whom we know nothing can be critical in implementing *our* decision?"—then go learn something about them.

Failure to do that cannot quite explain why CDC's identification of the liability problem, having been held down for so long, was then embraced without a hard look at its terms. The doctors drew from *Reyes* what we now know to have been too narrow a lesson, concentrating too much on the cost of awards stemming from duty to warn. The manufacturers drew a wider lesson; what might the courts pin on them next? The insurers drew a lesson wider still: verdicts aside, count up the claims, still more the suits! In OGC the implications were resisted or ignored for three months.