



# DIALOGUE ON DIVERSITY

## COMMENTARIES ON SEVERAL ADDITIONAL HEALTH CARE TOPICS

### THE ACA AND ITS TRAVAILS – MIGHT IT BE EXPEDIENTLY AMENDED?

The public discussion, as it appears, has been largely preempted by opponents of the existing law, whose insistence that the law, the Marketplaces, the effects of the “mandate”, all have “failed” in their function and in their purpose, so that the entire structure, now at the point of “imploding”, is to be put down as of no account. Premiums are too high to be borne by ordinary folks – but premiums and other pay elements are in fact determined by the costs of medical services and the incidence of disease, and are in this sense independent of the legal framework. The amounts of the effective premiums to particular consumers is a function principally, then, of the amount of subsidies which, by government fiat, can be directed to the consumers themselves, or to the insurers. The present statute provides for such subsidizing payments to both consumers and insurers. This problem is now one of the main blockages to effective insurance models, since the payments to insurers are intended by the statute to subsidize precisely the desired low level of premiums to consumers. They must be set so that the premium amounts (as adjusted by subsidies) will permit consumers of all income classes to buy policies on the Marketplaces, and at once will permit insurer participation to be viable for a number of companies (to ensure a due measure of competition in each market place). These payments are apparently now insufficient to the purpose, and the point of their amounts and even continuance is insistently placed in peril in the course of partisan bluster. Politically, however, there has been an unwillingness in the Congress to furnish the money (Money with a capital M) so that such subsidies, structured at a sufficiently robust level, can be offered. The action in the Federal Courts brought by the Congress, seeking to enjoin payment of the insurer subsidies is thus little effective in advancing the goals of health care, but is seen as a distraction from the job of appropriating sufficient funds to achieve the equilibrium described above. The system is scarcely at the point of “imploding”, but it is left to function at less than optimum efficiency.

### THE KAINE BILL ON REINSURANCE – HURRICANES AND HEALTH CARE

In the lore of ill weather Hurricanes are conceded to cause a certain quantum of harm concentrated in a confined district of the country, and thus imposing extraordinarily great expenses upon insurers with a concentration of policies in the affected district as they seek to satisfy the resultant claims. The insurers over the country (or even the globe), cognizant of the probability, however modest, of experiencing such events, find it expedient to combine in paying premiums into a system in which they themselves become the insured parties, so that the event of extraordinary claims from their customers, becomes a claim they assert against the stocks of past premiums contributed by all the participating companies. This is re-insurance. A bill recently introduced in the Senate – a development, dated June 15th, coming after the Symposium to which this report principally refers – by Senators Kaine of Virginia and Carper of Delaware, proposes a re-insurance arrangement among the health-care insurers, a combine presided over by a governmental agency, to regularize the rendering of requisite funds to the insurers so as to make a schedule of low premiums an economically viable course: when the insurer's expenses are greater than the current premium revenues, the insurer is compensated for the shortfall, but, what is of key import, the premiums charged to the customers on the Marketplaces and elsewhere, are left at the prescribed low level. This is the result intended by the direct governmental compensation to insurers that the political opposition has complained of. It would instead produce compensation out of a fund independently of the government budget for the year, and would operate by its own internal rules of intake and compensation, independently of any case-by-case decisions in the executive branch. Whatever the merits of the particular mechanisms proposed (and any question being left aside for the moment on the need for more effective subsidies to the consumers themselves), the strategy is appropriate, to focus repairs on quite specific points of friction in the large, already operating health-care system. The notion of upending the system in toto to root out a friction amenable to a simple repair is itself wanting in seriousness.

## A NOVEL CANCER TREATMENT – AN ESSAY IN PRECISION MEDICINE

One technical advance in cancer treatment – one among many being engineered in dozens of laboratories in the U.S. and Europe – is seen in the development over the last twenty years of a non-invasive treatment employing a discharge of low intensity electric impulses in the vicinity of certain tumors, in such power and sequence as to disrupt the division (multiplication) of cancer cells and, into the bargain, destroying the original offending cell. One treatment employing this non-(or minimally) invasive technology, for a form of lung cancer, has already gained FDA approval, while others are in Phase II and Phase III clinical trial stages. This innovative procedure is to be called into play to rescue a patient's case after a relatively feeble response of the tumor to conventional treatments, or as an initial treatment for tumors in hard to reach sites in the body.

### A MEGA-STUDY BY NIH

Much attention is in the air — some skeptical, while other views are voiced with high hopes — concerning the **AllofUs** project at the National Institutes of Health outside Washington. The project's plan is to assemble a corps of subjects numbering, if the project's goals are fully accomplished, at a million souls. With a body of data on each, produced by a vast protocol of queries, with up-dates compiled on each over some months, or years in time yet unrolling, the mass of items of data is to be filtered, juggled, and finally brought into an ordered schema – a task amenable only before the analytic powers of a planned phalanx of computers, running on instructions, or computer logic (aptly termed by the French “Logiciels”) designed by the shrewd and indefatigable efforts of the prize team of software experts – all with the purpose of teasing out trains of causation and association not readily visible to even the sharpest eye. But which promise to be the pioneering force making for cures and at once enabling scientific understanding of heretofore inaccessible refinement.

This is another feature of the application of information technology and statistical techniques in the study of health care phenomena. It lies in the newly conceived breed of Mega-Studies, surveying huge population-wide samples with the purpose of ferreting out the subtle trains of causation that promise to afford clues to prevention and cure of a variety of conditions and diseases. In particular the inquiries of the project propose to evolve a technology of “precision medicine,” in which the actions of specific compounds as they encounter the peculiar environment of a single patient can set off the unique interactions that, so it is calculated, will efficiently combat the illness of that particular patient. The current **AllofUs** project at NIH is perhaps the most prominent among these. What must be of especial concern to us in this species of studies is privacy, a perennial problem that in a new and more fearsome guise now comes roaring back to center stage big time. The NIH project's plan is to assemble a corps of subjects numbering, if the project's goals are fully accomplished, at a million souls. With a body of data on each, produced by a vast protocol of queries, and up-dated subject by subject through time future, the mass of items can be filtered, juggled, and finally brought into a useful ordering only by the extraordinarily powerful tools described above. The possible magnitude of a large scale disclosure is proportionate to the scientific achievement. The mode of newly refined processes of rendering data anonymous, of rationing access to carefully specified classes of investigators – and checking the whole perhaps unwieldy apparatus twice – much as a redoubtable St.Nick must keep tabs on a world of unruly children.

## PHARMACEUTICALS: ECONOMICS OF DEVELOPMENT AND PRICING

Editor's Note: PHARMACEUTICALS: THEIR DEVELOPMENT AND THEIR PRICING

The role of pharmaceuticals in the universe of medical practice has grown significantly over the last century, especially in the most recent decades, and basic research has advanced at such speed that a more powerful role yet is in prospect. See on this point the recent problem that is coming to obsess the persons observing the evolving conditions in this field. The present arsenal of anti-biotics are losing their heretofore

formidable strength as immunities to these are developing in the harmful germs. The solution might lie in the designing of antibiotics so cunning as to penetrate the modern germs' defense, only to confront in turn a new wave of immunities. But among the newest tendencies, operating in a quite different direction, is that of developing specialized viruses to be introduced near the infected spot, facultated to go on the attack, disrupting the reproductive mechanisms of the targeted bacteria, destroying both parent and intended progeny. This apparently has, in a radically experimental forum, effectively reduced otherwise uncontrollable infections that had showed themselves proof against all anti-biotics and other lines of attack. Another line of futuristic development in the pharmaceutical field is personalized, precision medicine. Here the goal is to fashion novel substances specifically designed to find and disrupt growths in the patient's body, here cancer being the most conspicuous targeted condition. The malady and the constitution of the patient intersect in the specific formulation of an antidote. See the note above on the NIH project on precision medicine and the AllofUs million-subject study.

This preliminary paragraph is intended to sketch the prospects, in an economic sense, for an ever advancing demand for pharmaceuticals. Our concern, as an initial matter, is with the choice of disease targets for drugs to be chosen for new development, the costs of developing these, and the determination of a pricing scheme — and the fashioning of a scheme of subsidies and industrial organization capable of solving the problems so identified. Research and engineering resources are in any short run limited; in a longer run these are subject to increase as needed to produce pharmaceuticals for a possibly enlarged variety of diseases, and for a possibly multiplied body of patients enabled to use them. In economic terms, a typical situation is one in which a short-run supply curve is highly inelastic, so that prices tend to be kicked sharply up as usage requirements rise while in a longer run the supply comes to be and more elastic, that is, responsive to needs (for apt skills and applicable machinery etc.) corresponding to increased usage, with a move to lower and lower prices. The common, and doubtless largely correct, understanding of the cost structure of the industry is that the development costs are high, especially when one factors in the massive, and somewhat costly job of recruiting subjects, statisticians and other resources for the elaborate choreography, and acute necessity, of clinical trials — all complicated by the fact that the success (particularly regulatory approval by the FDA or other official agency) of any drug is a chancy business and at that the revenue from the successful drugs must cover the costs of the many that are aborted in mid-development or suffer rejection in the clinical trials phase. In one way or another the difficulty is how to pay for the development and at once to enable production in fairly large quantities and to offer these to the universe of patients at less than astronomical prices. It is almost certain that, as in the case of orphan drugs (drugs targeting illnesses of extremely rare incidence, or diseases prevalent among populations unable to pay — under-developed economies, etc.), substantial subsidies are to be required from public funds, resources paid for by a form of general taxation.

[ This situation is analogous to the disputations on health care in its larger dimensions, and the efforts of legislators to “square the circle” — straining to cover more people at lower prices and with less money, keeping the physicians and drug factories prosperous into the bargain. The solution is inevitably an infusion of more money for subsidizing the costly care for persons unable otherwise to pay. The solution comes down to the question whether the ample economic resources of a very rich country should be given over in a sufficiently great quantity for the purpose. The country's 15-20 trillion productive capacity is in no danger of throwing us into destitution from the exercise. Another dimension, of course, is the role of prevention in diminishing the raging demand for medical services — which would render the need for funding correspondingly more moderate — but this effect is probably not fully available in any short run. The ACA specifically undertakes to put financial power into the preventive enterprise; whether the proposed substitutes would continue this is doubtful. ]

One form of solution to the pharmaceutical questions lies in turning the development process over to an independent entity, probably presided over by a public agency, even if, by contract, farming out the many development tasks to expensive experts and companies formed for the purpose and indeed the old-line

pharma firms themselves. (Here the choice of drugs to be worked on, incl. the “orphan drugs”, is probably to be made, if not simply by that agency, then by a commission of multi-partisan state officials and, more important, stakeholders of a great variety.)<sup>1</sup> Even now a good deal of the basic research (as distinct from the engineering work in devising the production mechanics) is performed by NIH and academic departments. And similarly the process of the clinical trials might well be conducted by an independent entity (this having the added effect, probably desirable, of removing any hint of a pharma firm’s trying its own case – a danger already minimized by FDA auditing). Under such a system the finished, approved drug would be available for production by any company, and the competition among them would tend to depress the price to the marginal costs of production.

A variant would be to throw the costs of development back on the producing companies by auctioning licenses (under a very subtly devised auctioning protocol!) to produce in such quantities as to cover the expense (or some determined, non-public portion thereof) of development incurred by the independent entity. This process, in either variant, would yield a price for the health care markets. Which could be cushioned to the extent needed, as any other element of the health care expenses, through some form of subsidy at the consumption point. An alternative schema, which would leave RD costs with an originating firm, would be to institute a compulsory licensing rule (pace the venerable patent system) – which might have to be coupled with an additional subsidy to the originating firm to cover its own (reasonable) RD expenses <sup>2</sup>after the ravages of the competitive frenzy among the firms of the industry upon promulgation of the compulsory license.

Could get to be, as any of these systems, a bit complicated, but that is what IT and the computer revolution were brought forth to puzzle out. Note that at many points in any feasible system subsidies from the public fisc are of the essence of the apparatus. This is the form that is assumed by the intuition that a decent society will pick up the wreckage that unexpected reverses and ill fortune and a weak or compromised constitution inevitably work in the affairs of its members. If legislators are strongly allergic to spending money, then they are a clog in the mechanics of the society in which public functions are an integral, seamlessly operating, and salutary part of the productive apparatus. It is scarcely the size of government that is the evil to be abated, but the degree to which the activities of government bias the choices of individuals – general rules, and money benefits rather than unnecessarily prescribed instructions will do the trick, if due ingenuity is exercised.

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<sup>1</sup> The choice of development projects for orphan and some other drugs would be affected by differing sentiments with respect to humanitarian and perhaps other considerations. A libertarian view would suggest fashioning a mechanism for throwing some number of drug items to the will of a revolving set of umpires. The problem of innovation in the face of a skeptical scientific establishment, (to the extent the candidate innovation is not a matter of romantic phantasy, better suited to films) is formally similar, and perhaps should be committed to a board of young experts in the field, smart and not yet attached (like barnacles to an ancient ship) to any institution or dogmatic conception of the science.

<sup>2</sup> And expenses “reasonably” incurred in unsuccessful drug development.